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*Attorneys for Plaintiffs*

**UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA  
WESTERN DIVISION**

REXINA MIZE, an individual; MINH  
NGUYEN, an individual;

Plaintiffs,

v.

MENTOR WORLDWIDE LLC;  
NEAL HANDEL, M.D.; and DOES 1-  
100, inclusive,

Defendants.

CASE NO: **2:17-cv-01747 DMG(KSx)**

**SECOND AMENDED  
COMPLAINT FOR DAMAGES**

- (1) NEGLIGENCE AND  
NEGLIGENCE PER SE
- (2) STRICT PRODUCTS  
LIABILITY- FAILURE TO  
WARN
- (3) STRICT PRODUCTS  
LIABILITY-  
MANUFACTURING DEFECT
- (4) BREACH OF IMPLIED  
WARRANTY
- (5) LOSS OF CONSORTIUM
- (6) MEDICAL BATTERY
- (7) FAILURE TO OBTAIN  
INFORMED CONSENT

**DEMAND FOR JURY TRIAL**

1  
2 Plaintiff REXINA MIZE, an individual, (hereinafter, “Plaintiff”), and Plaintiff  
3 MINH NGUYEN, an individual (hereinafter, “Spouse Plaintiff MINH NGUYEN” or  
4 “Plaintiff MINH NGUYEN”) by and through their attorneys, based on information  
5 and belief, and for causes of action against the Defendants, MENTOR WORLDWIDE  
6 LLC (“MENTOR”); NEAL HANDEL, M.D.; and DOES 1 through 100, inclusive,  
7 (hereinafter collectively referred to as “Defendants”) and each of them, hereby allege  
8 as follows:

## 9 10 **I. INTRODUCTION**

11 1. Plaintiff REXINA MIZE brings this action against Defendants, MENTOR  
12 WORLDWIDE LLC (“MENTOR”); NEAL HANDEL, M.D.; and DOES 1 through  
13 100, inclusive, (hereinafter collectively referred to as “Defendants”), and each of  
14 them, alleging the defective manufacturing of Mentor Worldwide LLC’s  
15 MemoryGel® Silicone Breast Implants, the pervasive and continuous failure to  
16 comport with the Premarket Approval Application (“PMA”) requirements imposed by  
17 the Food & Drug Administration (“FDA”), and failure to warn consumers of the  
18 known dangers.

19 2. Mentor Worldwide LLC touts itself as the global leader in aesthetic  
20 medicine, and the U.S. market leader in breast aesthetics. Founded in 1969, Mentor  
21 Corporation originally sold electronic laboratory instruments to measure activity  
22 within the nervous system. After introducing urethral catheters in the 1970s, they  
23 began delving into the plastic surgery field in the mid-1980s. Now, their breast  
24 implants have been used for millions of breast augmentation surgeries. Mentor  
25 Worldwide LLC is a leading supplier of medical products for the global aesthetic  
26 medicine market. The company develops, manufactures, and markets innovative,  
27 science-based products for aesthetics medical procedures.

28 3. Mentor is the only manufacturer whose breast implants are made in the

1 United States of America. The company is focused on three main areas: breast, body,  
2 and facial aesthetics. For over 20 years, more than 5 million women have used  
3 Mentor breast implants, making Mentor one of the global leaders in breast aesthetics.

4 4. In November of 2006, Mentor received FDA approval for its MemoryGel®  
5 (silicone gel-filled) Breast Implants for use in breast augmentation and reconstruction  
6 surgery.

7 5. On January 23, 2009, Mentor was acquired by the Johnson & Johnson  
8 Family of Companies, and is part of its Global Surgery Group. Mentor sought to be  
9 the trusted global leader in aesthetic medicine among both consumers and  
10 professionals by providing a broad range of innovative, science and clinical-based  
11 solutions to maintain, enhance, and restore self-esteem and quality of life.

12 6. In 1976, Congress passed the Medical Device Amendments ("MDA") to  
13 the Federal Food, Drug and Cosmetic ("FDCA"). Breast implants were placed into  
14 Class II devices and reviewed through the premarket notification (510(k)) process. In  
15 1988, in response to emerging safety concerns, the FDA re-classified breast implants  
16 to class III devices (requiring premarket approval, "PMA"), which was finalized in  
17 1991 when the FDA published a final 515(b) regulation calling for new silicone gel-  
18 filled breast implant applications for premarket approval.

19 7. Premarket approval (PMA) is the FDA process of scientific and regulatory  
20 review to evaluate the safety and effectiveness of Class III medical devices. Class III  
21 devices are those that support or sustain human life, are of substantial importance in  
22 preventing impairment of human health, or which present a potential, unreasonable risk  
23 of illness or injury. Due to the level of risk associated with Class III devices, the  
24 FDA has determined that general and special controls alone are insufficient to  
25 ensure the safety and effectiveness of Class III devices. Therefore, these Class III  
26 devices require a PMA under § 515 of the FDCA in order to obtain marketing  
27 clearance for the manufacturer to bring the product to market.  
28

1           8. In January 1992, the FDA announced a voluntary moratorium on silicone  
2 gel-filled breast implants, requesting that manufacturers stop supplying them and  
3 surgeons stop implanting them while the FDA reviewed new safety and effectiveness  
4 information that had been submitted. In April 1992, the FDA determined that none of  
5 the PMAs submitted for Mentor's MemoryGel Silicone Gel Breast Implants  
6 contained sufficient data to support approval, and therefore, Mentor's  
7 MemoryGel Silicone Gel Breast Implants were no longer marketed in the U.S,  
8 with the exception of use in reconstruction and revision patients. The FDA  
9 determined that access to silicone gel-filled breast implants for only  
10 reconstruction and revision patients could continue, but that implants used for these  
11 indications should be considered to be investigational devices, and women who  
12 received them should be followed through adjunct clinical studies.

13           9. According to the study entitled "Core Gel Study of the Safety and  
14 Effectiveness of Mentor Round Low Bleed Silicone Gel-filled Mammary Prostheses  
15 in Patients Who are Undergoing Primary Breast Augmentation, Primary Breast  
16 Reconstruction, or Revision," Clinical Trial Identifier No. NCT00753922, "In April  
17 1992, the moratorium was lifted but only for reconstruction and revision patients.  
18 Every patient implanted had to be part of an adjunct study, and had to be offered  
19 participation in a registry of gel-filled breast implant patients. In order to be implanted  
20 with gel-filled implants for *augmentation*, women had to be enrolled in a core clinical  
21 study." (emphasis added). *See Exhibit A*, Core Gel Study, pg. 3.

22           10. In December 2003, Mentor Worldwide LLC ("Mentor") submitted a PMA  
23 for its MemoryGel Silicone Gel Breast Implants. On November 17, 2006, the FDA  
24 approved Mentor's PMA, reference number P030053. *See Exhibit B*, Approval Letter.

25           11. This was the first time silicone gel-filled breast implants were available for  
26 augmentation, in addition to reconstruction and revision, since the moratorium was  
27 established in 1992. As conditions of approval, Mentor was required to conduct six  
28 post-approval studies to further characterize the safety and effectiveness of their

MemoryGel Silicone Gel Breast Implants and to answer scientific questions that the premarket clinical trials were not designed to answer. The following post-approval study requirements were listed by the FDA in the PMA granting Mentor's MemoryGel™ Silicone Gel-Filled Breast Implants:

- 1) Core postapproval study (core study)- To assess long-term clinical performance of breast implants in women that enrolled in studies to support premarket approval applications. These studies were designed to follow women for 10 years after initial implantation.
- 2) Large postapproval study (large study)- To assess long-term outcomes and identify rare adverse events by enrolling more than 40,000 silicone gel-filled breast implant patients, following them for 10-years.
- 3) Device failure studies (failure study)- To further characterize the modes and causes of failure of explanted devices over a 10-year period.
- 4) Focus group study- To improve the format and content of the patient labeling.
- 5) Informed decision process - To monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants.
- 6) Mentor adjunct study - To provide performance and safety information about silicone gel-filled breast implants provided to U.S. women from 1992-2006, prior to approval, when implants could only be used for reconstruction and replacement of existing implants.

12. Mentor failed to report adverse events from the six new or ongoing studies commissioned as part of the implant's PMA approval, which would have led to reports suggesting the device's contribution to serious injury.

13. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to a medical device rests with the manufacturer. The manufacturer has superior, and in many cases exclusive, access to

1 the relevant safety and efficacy information, including post market complaints and  
2 data.

3 14. To fulfill this essential responsibility, a manufacturer must vigilantly  
4 monitor all reasonably available information. The manufacturer must closely evaluate  
5 the post-market clinical experience with the device and its components and timely  
6 provide updated safety and efficacy information to the U.S. Food and Drug  
7 Administration (“FDA”), the healthcare community and to consumers. The  
8 manufacturer also must carefully monitor its own manufacturing operations and  
9 quality controls to ensure that the device uniformly conforms to the manufacturer’s  
10 approved design, as well as its representations and warranties and with specifications  
11 of approval.

12 15. When monitoring and reporting adverse events as required by both federal  
13 regulations and California law, time is of the essence. The purpose of monitoring a  
14 product’s post-market experience is to detect potential safety signals that could  
15 indicate to the manufacturer and the medical community that a public safety problem  
16 exists. If a manufacturer waits to report post-market information, even for a few  
17 weeks or months, that bottleneck could mean that researchers, regulatory bodies, and  
18 the medical community are years behind in identifying a public safety issue  
19 associated with the device. In the meantime, more patients are harmed by using the  
20 product without understanding its true risks. This is why a manufacturer must not  
21 only completely and accurately monitor, investigate and report post-market  
22 experience, but it must also report the data as soon as it is received.

23 16. Defendants failed to fulfill their post-market responsibilities to adequately  
24 conduct, monitor, follow-up, and warn about serious health risks regarding their  
25 MemoryGel Silicone Gel Breast Implants, which were conditions of approval  
26 specified by the FDA. *See Exhibit B*, pg. 2-4.

27 17. Defendant NEAL HANDEL, M.D., upon information and belief, failed to  
28 provide Ms. Mize true and correct material information regarding the risks, safety,

1 and dangers of undergoing a breast implant procedure. Upon information and belief,  
 2 Defendant NEAL HANDEL, M.D. failed to inform Ms. Mize that she was allegedly  
 3 part of one of Defendant Mentor's clinical studies, and further failed to inform her  
 4 before she underwent the implanting procedure that the silicone breast implants were  
 5 not yet FDA-approved.

## 6 7 **II. PARTIES, JURISDICTION AND VENUE**

8 18. At all times relevant hereto, Plaintiff REXINA MIZE is and was a citizen  
 9 and resident of Los Angeles County, California.

10 19. At all times relevant hereto, Spouse Plaintiff MINH NGUYEN is married  
 11 to, and the husband of, Plaintiff REXINA MIZE, and is and was a citizen and resident  
 12 of Los Angeles County, California.

13 20. Defendant NEAL HANDEL, M.D. (hereinafter "Dr. Handel") was and is  
 14 licensed to practice medicine in the State of California, and does practice medicine in  
 15 this State. Upon information and belief, Dr. Handel practices medicine at 9201 W.  
 16 Sunset Blvd., Suite 214, West Hollywood, California 90069. It is further alleged upon  
 17 information and belief, that Dr. Handel practices cosmetic surgery in Beverly Hills  
 18 and Santa Barbara, California.

19 21. Upon information and belief, Dr. Handel performs outpatient surgical  
 20 procedures at an in-office surgical suite at the Sunset Hills Surgery Center located in  
 21 Los Angeles, California, and Coast Presidio Surgical Center located in Santa Barbara,  
 22 California.

23 22. Upon further information and belief, Dr. Handel is an Associate Clinical  
 24 professor at UCLA Medical School's Division of Plastic Surgery.

25 23. Mentor Corporation was a corporation located in Minneapolis, Minnesota.  
 26 Defendant Mentor Worldwide LLC, upon information and belief, is the successor in  
 27 interest of Mentor Corporation.

28 24. Defendant MENTOR WORLDWIDE LLC is a limited liability company,



1 and is deemed a citizen of the state of its members. It is incorporated under the laws  
2 of the State of Delaware, with its principal place of business located at 201 Mentor  
3 Drive, Santa Barbara, California, 93111, and its headquarters located at 33  
4 Technology Drive, Irvine, California, 92618.

5 25. Defendant Mentor moved its headquarters to Santa Barbara, California in  
6 1985.

7 26. Defendant Mentor is a wholly-owned subsidiary of Johnson & Johnson.  
8 Johnson & Johnson, through its subsidiary Ethicon, Inc., acquired Mentor  
9 Corporation. Mentor Texas, Inc. is a wholly owned subsidiary of the Mentor  
10 Corporation, located at 201 Mentor Drive, Santa Barbara, California 93111.

11 27. The Johnson & Johnson corporate family structure includes a multitude of  
12 wholly-owned subsidiaries and affiliated companies all over the world, including  
13 Mentor Worldwide, LLC, which is based and operates out of California.

14 28. ETHICON, INC. is a subsidiary of Johnson & Johnson. Under the terms of  
15 the acquisition of Defendant Mentor, Defendant Mentor was expected to operate as a  
16 stand-alone business unit reporting through ETHICON, Inc., a Johnson & Johnson  
17 company, and leading provider of suture, mesh and other products for a wide range of  
18 surgical procedures.

19 29. The true names and/or capacities, whether individual, corporate, associate  
20 or otherwise of Defendants DOES 1 through 100, inclusive, are unknown to Plaintiffs  
21 at this time, who therefore sue said Defendants by such fictitious names. Plaintiffs are  
22 informed and believe, and thereupon allege, that each of the Defendants fictitiously  
23 named herein as a DOE is legally responsible, negligently or in some other actionable  
24 manner, for the events and happenings hereinafter referred to, and thereby  
25 proximately caused the injuries and damages to Plaintiffs as hereinafter alleged.  
26 Plaintiffs will seek leave of court to amend this Complaint to insert the true names  
27 and/or capacities of such fictitiously named Defendants when the same have been  
28 ascertained.



1           30. Hereinafter, the aforementioned Defendants may collectively be referred  
2 to as “Defendants.”

3           31. At all relevant times, each Defendant acted in all aspects as the agent and  
4 alter ego of each other.

5           32. The combined acts and/or omissions of each Defendant resulted in  
6 indivisible injuries to Plaintiff. Each of the above-named Defendants is a joint  
7 tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiff for the  
8 negligent acts and omissions alleged herein. Each of the above-named Defendants  
9 directed, authorized or ratified the conduct of each and every other Defendant.

10           33. At all relevant times, Defendants acted in concert with one another in the  
11 State of California to fraudulently convey false and misleading information  
12 concerning Mentor MemoryGel Silicone Gel Breast Implants (the “product”), and to  
13 conceal the risks of serious adverse events associated with Mentor MemoryGel  
14 Silicone Gel Breast Implants from the public, Plaintiffs, physicians, and other  
15 healthcare providers. These concerted efforts resulted in significant harm to Plaintiffs.  
16 But for the actions of Defendants, individually, jointly, and in concert with one  
17 another, Plaintiffs would not have been implanted with Mentor MemoryGel Silicone  
18 Gel Breast Implants and would not have suffered severe injuries.

19           34. This Court has personal jurisdiction over Defendants. Defendants are and  
20 were at all relevant times residents of and/or authorized to conduct business in the  
21 State of California and Defendants conducted such business within the State including  
22 the performance of acts that caused or contributed to the harm giving rise to this  
23 action.

24           35. At all times material hereto, Defendants maintained systematic and  
25 continuous contacts in this judicial district, regularly transacted business within this  
26 judicial district, employed numerous individuals in this district and regularly availed  
27 themselves of the benefits of this judicial district. Defendants received substantial  
28 financial benefit and profits as a result of the designing, formulating, testing,  
packaging, labeling, producing, creating, constructing, making, assembling,

1 advertising, clinical testing, marketing, promoting, distributing, manufacturing, and  
2 selling the product in this district and throughout the United States.

3 36. At all times material hereto, the action arises from obligations that arise  
4 out of, or are connected with, Defendants' activities within the State of California.

5 37. Plaintiff's claims arise out of and/or are related to Defendants' California-  
6 related forum activities. Plaintiffs are informed and believe and on that basis allege  
7 that Defendants have purposefully directed their activities at this forum State, and the  
8 exercise of jurisdiction is reasonable and would not offend the traditional notions of  
9 fair play and substantial justice. Plaintiffs are informed and believe and on that basis  
10 allege that Defendants have purposefully availed themselves of the privileges and  
11 benefits of conducting activities with the forum State, and have invoked the benefits  
12 and protections of its laws.

13 38. Defendant Dr. Handel is licensed to practice medicine in this State, and  
14 does practice medicine in this State. Plaintiffs are citizens of this State. Additionally,  
15 a substantial part of the events giving rise to Plaintiffs' claims occurred in California.

16 39. Venue is proper in the county where Plaintiffs' injuries occurred, or where  
17 the defendants, or some of them, reside under California Code of Civil Procedure §  
18 395 ("CCP"). Venue is proper in Los Angeles County in accordance with CCP § 395,  
19 because the injuries alleged herein arose from conduct that occurred in this county,  
20 Ms. Mize's implantation and removal surgeries occurred in this county, and  
21 Defendant Dr. Handel practices medicine at an office located in this county.

### 22 **III. DELAYED DISCOVERY**

23 40. Plaintiff exercised reasonable diligence in investigating her injuries, and  
24 could not have discovered that her injuries were caused by the product at an earlier  
25 time. The discovery rule applies to toll the running of the statute of limitations until  
26 Plaintiff knew, or through the exercise of reasonable care and diligence, should have  
27 known of the existence of her claims against all Defendants.

28 41. The nature of Plaintiffs injuries and subsequent damages, and their causal

1 relationship to the product were not, and could not, have been discovered through  
2 reasonable care and diligence.

3 42. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, the cause  
4 of her injuries caused by the product, or the tortious nature of the conduct causing  
5 those injuries, until less than the applicable limitations period prior to the filing of this  
6 action.

7 43. Plaintiff did discover that her injuries were related to her silicone breast  
8 implants until after December 6, 2016.

9 44. None of Plaintiff's doctors previously connected her injuries with her  
10 silicone breast implants.

11 45. Dr. Handel did not maintain records for Plaintiff past the requisite time  
12 required for physicians in California. Records do not exist for Plaintiff's implanting  
13 surgery, pre-surgery visits, or post-op visits. Therefore, the information concerning  
14 Ms. Mize's involvement in an adjunct study was not available to her through review  
15 of medical records.

16 46. Furthermore, upon information and belief, Plaintiff was only given  
17 information on the data stickers showing the lot number, manufacturer and date of  
18 implant. Plaintiff was never advised that she was part of the adjunct study and never  
19 told to follow up with Dr. Handel or Mentor for purposes of that study.

20 47. The Mentor Adjunct study was originally designed for women with breast  
21 reconstruction and revision surgery following breast cancer treatment. At the time of  
22 Plaintiff's implantation she was not a proper candidate for the Adjunct study, she paid  
23 for her implants, and was not given any information to alert her that she was a study  
24 participant.

25 48. Dr. Handel never discussed with Plaintiff anything she was required to  
26 sign prior to going into her implant surgery.

27 49. Defendants, through their affirmative misrepresentations and omissions,  
28 actively concealed from Plaintiff and her healthcare providers the true and significant

1 risks associated with the product.

2 50. Defendant Dr. Handel, through his affirmative misrepresentations and  
3 material omissions, actively concealed from Plaintiff Ms. Mize the true nature of the  
4 surgical procedure she underwent for implantation of her Mentor MemoryGel silicone  
5 gel-filled breast implants. Defendant Dr. Handel did not provide to her the material  
6 facts surrounding her breast implant procedure, did not obtain full informed consent  
7 for the surgery, and did not inform Ms. Mize that she was allegedly part of Mentor's  
8 clinical study.

9 51. Under CCP § 340.5, the statute of limitations against a healthcare provider  
10 based upon negligence commences three years after the date of injury or one year  
11 after the plaintiff discovers, or through the use of reasonable diligence should have  
12 discovered, the injury. In no event shall the time for commencement of a legal action  
13 exceed three years unless tolled for any of the following: (1) upon proof of fraud, (2)  
14 intentional concealment, or (3) the presence of a foreign body.

15 52. Defendant Dr. Handel intentionally concealed material information from  
16 Ms. Mize. She did not discover that she was allegedly a participant in Mentor's  
17 Adjunct Study until Mentor's counsel informed Plaintiffs' counsel on June 30, 2017  
18 that Ms. Mize was allegedly part of Mentor's Adjunct clinical study, which Dr.  
19 Handel failed to disclose to Ms. Mize at the time of her implanting surgery. This  
20 newly discovered information was relayed to Ms. Mize on June 30, 2017. As such,  
21 this action is timely filed.

22 53. Further, Defendants are estopped from asserting a statute of limitations  
23 defense because all Defendants fraudulently concealed from, and misrepresented to,  
24 Plaintiff the connection between the injuries sustained and the Defendants' tortious  
25 conduct.

26  
27 **IV. FACTUAL ALLEGATIONS: MEMORYGEL® SILICONE BREAST**  
28 **IMPLANTS**

## A. Regulatory History of Silicone Breast Implants in The U.S.

YEAR	EVENT
1960s	The first silicone breast implants are developed by two plastic surgeons.
1976	Congress passed the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act. Breast implants were placed into Class II and reviewed through the premarket notification [510(k)] process.
1982- January	FDA proposes to classify silicone breast implants into Class III category which would require manufacturers to prove their safety and efficacy in order to keep them on the market.
1988- June	In response to emerging safety concerns, the FDA re-classified breast implants to class III devices (requiring premarket approval). However, in accordance with the law, they continued to be reviewed through the 510(k) process until the FDA issued a rule calling for submission of premarket approval applications (PMAs).
1991-April	The FDA issued a final rule calling for submission of PMAs for silicone gel-filled breast implants.
1991-September	The FDA concluded that the silicone breast implant manufacturers' safety data did not prove the devices are safe- or harmful. Manufacturers are told to submit further data.
1991-November	The FDA held an Advisory Panel meeting to discuss several PMAs for silicone gel-filled breast implants. While the panel concluded that the manufacturers had failed to provide adequate safety and effectiveness data for their implants, they unanimously recommended that the FDA permit the implants to remain on the market.
1992-January	The FDA announced a voluntary moratorium on silicone gel-filled breast implants, requesting that manufacturers stop supplying them and surgeons stop implanting them, while the FDA reviewed new safety and effectiveness information that had been submitted.
1992-February	Based on new information, the FDA held a second Panel meeting to re-evaluate the safety of silicone gel-filled breast implants. This time the panel recommended that silicone gel-filled breast implants be removed from the market pending further evaluation of the new data.
1992-April	The FDA commissioner lifted the moratorium on silicone breast implants. The only women allowed to receive implant surgery are those undergoing breast reconstruction. All of the implant recipients must become part of a scientific protocol. The FDA concluded: <ul style="list-style-type: none"> <li>•None of the PMAs submitted for silicone gel-filled breast implants contained sufficient data to support approval.</li> <li>•Access to silicone gel-filled breast implants should continue for patients undergoing breast reconstruction or for replacement of existing silicone gel-filled breast implants (revision). Implants used for these indications should be considered to be investigational devices, and women who received them should be followed through adjunct clinical studies.</li> </ul>

1	1992-July	The FDA approved Mentor's Adjunct Study protocol for its silicone gel-filled breast implants for reconstruction and revision patients only.
2	1999	Silicone gel-filled implants remain off the market in the U.S. pending manufacturer safety studies.
3	2000-August	The FDA approved Mentor's IDE study (i.e., Core Study) for its silicone gel-filled breast implants for a limited number of augmentation, reconstruction, and revision patients at a limited number of sites. This is the Core Study for submission P030053.
4		
5	2003-December	Mentor submitted a PMA (P030053) for its silicone gel-filled breast implants.
6		
7	2005-April	The FDA held an Advisory Panel meeting to review Allergan's updated PMA and Mentor's PMA. In a 5 to 4 vote, the panel did not recommend approval of Allergan's PMA (due to a concern with one style in the application). In a 7 to 2 vote, the panel recommended approvable with conditions for Mentor's PMA. The panel recommended that FDA require conditions including a minimum age requirement for augmentation and Post-Approval Studies.
8		
9		
10		
11	2006-November	The FDA approved Allergan and Mentor's PMAs for silicone gel-filled breast implants. This was the first time silicone gel-filled breast implants were available for augmentation, in addition to reconstruction and revision, since the moratorium was established in 1992. As conditions of approval, each manufacturer was required to conduct 6 post-approval studies to further characterize the safety and effectiveness of their silicone gel-filled breast implants and to answer scientific questions that the premarket clinical trials were not designed to answer.
12		
13		
14		
15		
16	2011-January	The FDA issued a Safety Communication on anaplastic large cell lymphoma (ALCL) in women with breast implants. Based on a review of the scientific literature, the FDA believes that women with breast implants may have a very small but increased risk of developing this disease in the scar capsule adjacent to the implant.
17		
18		
19	2011-June	The FDA issued an Update on the Safety of Silicone Gel-Filled Breast Implants. It included preliminary results of the post approval studies Allergan and Mentor were required to perform as conditions of their silicone gel-filled breast implant 2006 approval.
20		
21	2011-August	The FDA held an Advisory Panel meeting to discuss and receive recommendations on postmarketing issues related to silicone gel-filled breast implants. Also discussed at this meeting were innovative methodological approaches to postmarket studies regarding silicone gel breast implants, as well as key long-term safety issues associated with silicone gel breast implants in the real-world setting.
22		
23		
24		
25	2013-June	The FDA approved Mentor's PMA for a silicone gel-filled breast implant that uses a more cohesive silicone gel, compared to their previously approved breast implant. As a condition of approval, the manufacturer was required to conduct a series of post-approval studies to further characterize the safety and effectiveness of their breast implant and to answer scientific questions that the premarket clinical trial was not designed to answer.
26		
27		
28		



## B. Background About Silicone Breast Implants

54. Silicone is the name given to a family of synthetic polymers composed of a repeating Si-O backbone and carbon-linked side groups. Si-C bonds do not exist in nature, but can be formed under appropriate manufacturing conditions.

55. Silicon was discovered by Jöns Jacob Berzelius, a Swedish chemist, in 1824 by heating chips of potassium in a silica container and then carefully washing away the residual by-products. Silicon is the seventh most abundant element in the universe and the second most abundant element in the earth's crust. Today, silicon is produced by heating sand ( $\text{SiO}_2$ ) with carbon to temperatures approaching  $2200^\circ\text{C}$ .

56. It is most widely distributed in dusts, sands, planetoids, and planets as various forms of silicon dioxide (silica) or silicates. Over 90% of the Earth's crust is composed of silicate minerals, making silicon the second most abundant element in the Earth's crust after oxygen.

57. A breast implant is a prosthesis product used to change the size, shape, and contour of a woman's breast. There are three general types of breast implant devices, defined by their filler material: saline solution, silicone gel, and composite filler.

58. Generally, there are five generations of silicone breast implants. Upon information and belief, the various generations exemplified the following characteristics:

- **First Generation (1962-1970)**
  - Thick, two-piece shell
  - Smooth surface with Dacron fixation patches
  - Anatomically shaped (teardrop)
  - Viscous silicone gel
  - Featured teardrop-shaped sac
- **Second Generation (1970-1982)**
  - Thin, slightly permeable shell
  - Smooth surface (no Dacron patches)
  - Less viscous silicone gel



- **Third Generation** (1982-1992)
  - Thick, strong, low-bleed shell
  - Smooth surface
  - Round shape
  - More viscous silicone gel
- **Fourth Generation** (1993-present)
  - Thick, strong, low-bleed shell
  - Smooth and textured surfaces
  - Round and anatomically shaped
  - More viscous (cohesive) silicone gel
  - Elastomer-coated implant shells
- **Fifth Generation** (1993-present)
  - Thick, strong, low-bleed shell
  - Smooth and textured surfaces
  - Round and diverse anatomical shapes
  - Enhanced cohesive and form-stable silicone gel

59. Silicone gel-filled breast implants have a silicone outer shell that is filled with silicone gel. They come in various sizes and can have either a smooth or textured shell. Silicone gel-filled breast implants are approved for breast augmentation in women age 22 or older and for breast reconstruction in women of any age.

60. While silicone breast implants have been in use since the 1960s, it was not until 1976 that legislation was passed giving the FDA responsibility to oversee the safety of medical devices. In 1982, the FDA proposed that the manufacturers of implants provide additional evidence on the safety of breast implants. In 1988, the FDA mandated the manufacturers provide such evidence. This ruling was not enforced until 1991. The head of the FDA asked for a voluntary moratorium on the use of silicone gel-filled implants. He banned their use except in clinical trials of breast reconstruction after cancer surgery. He stated that the ban was implemented not because gel-filled implants had been shown to be unsafe, but rather, because the manufacturers had not provided adequate data proving their safety.

61. The FDA, after the enactment of the MDA, allowed the use of silicone-filled breast implants as long as manufacturers later provided "reasonable assurance" of the products' safety and effectiveness. 21 U.S.C. §360e(d)(2). In 1988, in response

1 to emerging safety concerns, the FDA re-classified breast implants to class III devices  
 2 (requiring premarket approval), which was finalized in 1991 when the FDA  
 3 published a formal 515(b) regulation allowing for PMAs for silicone gel-filled  
 4 breast implants.

5 62. In 1992, the FDA determined that there was insufficient data for approval,  
 6 and Mentor's MemoryGel Silicone Gel Breast Implants were no longer marketed in  
 7 the U.S., with the exception of use in reconstruction and revision patients.

8 63. Upon information and belief, approximately 5 to 10 million women  
 9 worldwide have breast implants. According to the American Society of Plastic  
 10 Surgeons National Clearinghouse of Plastic Surgery Procedural Statistics, there were  
 11 296,203 breast augmentation procedures and 93,083 breast reconstruction procedures  
 12 performed in the United States in 2010.

### 13 **C. Pre-Market Approval**

14 64. Pre-market Approval ("PMA") is the FDA process of scientific and  
 15 regulatory review to evaluate the safety and effectiveness of Class III medical devices.  
 16 See 21 U.S.C. § 515(b); 21 CFR § 814.3(e).

17 65. A PMA application must contain certain information which is critical to the  
 18 FDA's evaluation of the safety and efficacy of the medical device at issue. A PMA  
 19 and/or PMA Supplement application must provide:

- 20 a. proposed indications for use;
- 21 b. device description including the manufacturing process;
- 22 c. any marketing history;
- 23 d. summary of studies (including non-clinical laboratory studies, clinical  
 24 investigations involving human subjects, and conclusions from the study  
 25 that address benefit and risk considerations);
- 26 e. each of the functional components or ingredients of the device;
- 27 f. methods used in manufacturing the device, including compliance with  
 28 current good manufacturing practices; and

g. any other data or information relevant to an evaluation of the safety and effectiveness of the device known or that should reasonably be known to the manufacturer from any source, including information derived from investigations other than those proposed in the application and from commercial marketing experience.

66. According to the FDA, a Class III device that fails to meet the Conditional Premarket Approval (“CPMA”) requirements after marketing is considered to be adulterated under § 501(f) of the Federal Food, Drug and Cosmetic Act (“FDCA”) and cannot continue to be marketed.

67. Defendants are required to comply with all FDA post –marketing requirements for Class III medical devices. Approval of a device through the PMA process signals the beginning, not the end, of a device manufacturers duties to patients under both federal regulations and established California law.

68. Defendants’ post-approval obligations under federal law included, but are not limited to:

- a. report to the FDA information suggesting that one of the Manufacturer’s devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur, 21 CFR §§ 803.50 et seq.;
- b. monitor the product after pre-market approval and to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 CFR §§ 814 et seq.;
- c. submit a PMA Supplement for any change in Manufacturing Site, 21 CFR §§ 814.39 et seq.;
- d. establish and maintain quality system requirements to ensure that quality requirements are met, 21 CFR § 820.20 et seq.;
- e. establish and maintain procedures for validating the device design,

1 including testing of production units under actual or simulated use  
 2 conditions, creation of a risk plan, and conducting risk analyses, 21 CFR  
 3 §§ 820.30 et seq.;

4 f. document all Corrective Action and Preventative Actions taken by the  
 5 Manufacturer to address non-conformance and other internal quality  
 6 control issues, 21 CFR §§ 820.100 et seq.;

7 g. establish internal procedures for reviewing complaints and event reports,  
 8 21 CFR §§ 820.198, §§ 820.100 et seq. and §§ 820.20 et seq.;

9 h. establish Quality Management System (QMS) procedures to assess  
 10 potential causes of non-conforming products and other quality problems,  
 11 21 CFR §§820.70 et seq. and 21 CFR §§ 820.90 et seq.;

12 i. report on Post Approval Studies in a timely fashion, 21 CFR §§ 814.80 et  
 13 seq.; and

14 j. advertise the device accurately and truthfully, 21 CFR §§ 801 et seq.

15 69. Had Defendants fulfilled these obligations, which federal and state law  
 16 required them to do, Plaintiff's injuries would not have occurred. Defendants failed to  
 17 do so.

18 70. Under state law, including California law, Defendants had a duty to  
 19 exercise reasonable care in adequately warning Plaintiff and/or Plaintiff's physician  
 20 about the dangers of Mentor MemoryGel silicone breast implants that were known or  
 21 knowable to Defendants at the time of distribution. Under both federal and state law,  
 22 Defendants also have a post-market duty to monitor and report adverse events and  
 23 risks associated with the device. Despite having knowledge and possession of  
 24 evidence that showed the use of Mentor MemoryGel silicone breast implants were  
 25 dangerous and likely to place consumers' health at serious risk, Defendants failed to  
 26 disclose and warn of the health hazards and risks associated with the product. Instead,  
 27 Defendants marketed, advertised, and promoted the product while failing to monitor,  
 28 warn, or otherwise ensure the safety and efficacy of its users in violation of state law,

1 including California law, and FDA regulations.

2 71. The FDA's initial approval of a device label amounts to a finding by the  
3 FDA that the label is adequate for purposes of gaining initial approval to market the  
4 device. It does not represent a finding by the FDA that the label can never be deemed  
5 inadequate after approval as new safety information from the real world experience  
6 with the device becomes available to the manufacturer. Sound reasons support these  
7 principles: there are products, such as Mentor MemoryGel silicone breast implants,  
8 for which evidence of the device's defects comes to light only after the device is used  
9 in a real world setting.

10 72. After Mentor MemoryGel silicone breast implants received pre-market  
11 approval, Defendants were at all times responsible for maintaining the labeling  
12 Mentor MemoryGel silicone breast implants in light of the most current risk  
13 information obtained from the real world clinical experience with the device. There is  
14 no federal requirement that a manufacturer maintain its original warning language in  
15 the face of new safety information. Nor does federal law give device manufacturers a  
16 right to market their device using the label originally approved by the FDA when new  
17 post-market information bearing on the safety of the device comes to light. To the  
18 contrary, the FDCA required Defendants not to sell a device that was accompanied by  
19 an inadequate warning or had a label that was false or misleading in any respect, 21  
20 U.S.C. § 352(a), (f)(2), because such a deficient warning rendered the device  
21 "misbranded" under 21 U.S.C. § 331, as well as the Sherman Food, Drug, and  
22 Cosmetic Laws. West's Ann. Cal. Health & Safety Code § 111330.

23 73. Defendants were at all times responsible for maintaining the labeling of  
24 the product, and had the ability under federal law, and the duty under state and federal  
25 law, to directly warn healthcare providers and consumers unilaterally updating the  
26 labeling of Mentor MemoryGel silicone breast implants to reflect newly acquired  
27 safety information without advance approval by the FDA.. Accordingly, Defendants  
28 had the ability to file a "Special PMA Supplement – Changes Being Effected"

1 (“CBE”) which allows Defendants to unilaterally update the labeling to reflect newly  
 2 acquired safety information without advance approval by the FDA. 21 C.F.R. §  
 3 814.39(d). These changes include:

- 4 a. labeling changes that add or strengthen a contraindication, warning,  
 5 precaution, or information about an adverse reaction for which there is  
 6 reasonable evidence of a causal association;
- 7 b. labeling changes that add or strengthen an instruction that is intended to  
 8 enhance the safe use of the device;
- 9 c. labeling changes that ensure it is not misleading, false, or contains  
 10 unsupported indications; and
- 11 d. changes in quality controls or manufacturing process that add a new  
 12 specification or test method, or otherwise provide additional assurance of  
 13 purity, identity, strength, or reliability of the device.

14 74. Defendants breached their duties under federal law and state law,  
 15 including California law, to maintain labeling that: (a) added instructions for use that  
 16 would enhance the safe use of the device; and (b) added descriptions of adverse  
 17 events to ensure that the labeling was not false or misleading.

18 75. The FDCA requires medical device manufacturers like Defendants to  
 19 maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i,  
 20 including submitting Adverse Reaction Reports, 21 C.F.R. § 803.50, and establishing  
 21 internal procedures for reviewing complaints and event reports, 21 C.F.R. §  
 22 820.198(a). Specifically, 21 C.F.R. § 803.50 requires a manufacturer to report  
 23 information no later than 30 days after it is received, from any source, if that  
 24 information suggests that the device may have contributed to a serious injury, or has  
 25 malfunctioned and the malfunction would be likely to contribute to a serious injury if  
 26 it were to recur.

27 76. The FDA publishes the adverse events and MDRs in a public, searchable  
 28 Internet database called MAUDE and updates the report monthly with “all reports

1 received prior to the update.” The general public, including physicians and patients,  
2 may use the MAUDE database to obtain safety data on medical devices.

3 **D. Mentor MemoryGel Silicone Breast Implants & PMA Approval**

4 77. Mentor MemoryGel Breast Implants are filled with Mentor’s proprietary  
5 cohesive gel, and contain the latest generation of silicone. They are prefilled with  
6 Mentor’s uniquely formulated silicone gel. This gel is not like a liquid or a semi-  
7 liquid. Instead, it is a cohesive gel that closely resembles breast tissue.

8 78. Upon information and belief, at all relevant times, Mentor designed,  
9 manufactured, tested, and distributed Mentor breast implants, including the Mentor  
10 MemoryGel Silicone Gel Breast Implants.

11 79. Defendant Mentor filed a premarket approval application on or about  
12 December 12, 2003.

13 80. On November 17, 2006, the FDA approved Mentor’s PMA for  
14 MemoryGel Silicone Gel-Filled Breast Implants, P030053, which allowed Mentor to  
15 market the product. *See Exhibit B*, Approval Letter.

16 81. As conditions of approval, Mentor was required to conduct six post-  
17 approval studies to further characterize the safety and effectiveness of their  
18 MemoryGel Silicone Gel Breast Implants and to answer long term questions that the  
19 premarket clinical trials were not designed to answer. The FDA required Mentor to  
20 (1) Continue and complete their core post-approval study, (2) Conduct a large post-  
21 approval study to assess long-term outcomes and identify rare adverse events by  
22 enrolling 41,900 silicone gel-filled breast implant patients and 1,000 saline-filled  
23 breast implant patients and follow them for 10 years, (3) Conduct a device-failure  
24 study in concert with their large post-approval study to further identify the modes and  
25 causes of failure of explanted devices over the 10-year period, (4) Complete a focus-  
26 group study to evaluate how easily patients understand the information in the  
27 informed decision brochure about the risks associated with the use of silicone breast  
28 implants, (5) Complete an informed decision study to monitor the process of how



1 patient labeling is distributed to women considering silicone gel-filled breast  
2 implants, and (6) Complete the Mentor adjunct study, which was in place after 1992,  
3 when the FDA allowed Mentor to market silicone gel-filled breast implants for  
4 reconstruction after mastectomy, correction of congenital deformities, or replacement  
5 of existing implants. Women who received silicone gel-filled breast implants for these  
6 purposes were enrolled in Adjunct Studies so that data about device performance and  
7 safety could be collected. Participant enrollment began in 1992 for Mentor. As a  
8 condition of approval of silicone gel-filled breast implants in 2006, Mentor was  
9 required to close enrollment of new patients into the Adjunct Studies but continue to  
10 follow existing participants through their 5-year post-implant evaluations.

11 **1) Core Post Approval Study**

12 82. As one of the conditions of approval, the FDA specifically required  
13 Mentor to continue their Core Study, which had been underway since September 2000  
14 and published in Mentor's PMA. *See Exhibit C*, Core Study. There were 1008  
15 patients enrolled in that study. Mentor was to continue the study until all patients had  
16 completed their 10-year evaluation in order to assess the long-term clinical  
17 performance of their product. There were to be 11 follow-up visits, at 6 months post-  
18 operation, and annually 1 year to 10 years after surgery. Mentor was required to  
19 collect data via annual physician follow-up evaluations. The primary changes to the  
20 protocol from premarket to post approval were that all non-MRI patients should have  
21 an MRI at years 6, 8, and 10 and that all patients who were explanted without  
22 replacement were to be evaluated through 10 years. Mentor was also required to  
23 update their patient and physician labeling to reflect the results of the 5 and 10-year  
24 Core Study findings and to report to the FDA significant new information regardless  
25 of when the information became available.

26 83. According to the FDA website, the core post-approval study follow-up  
27  
28

1 rates at 9 years post-implant were only 59 percent.<sup>1</sup> However, the core post-approval  
2 study page states that the follow-up rate at 10 years post-implant was 62 percent. *See*  
3 *Exhibit C*, pg. 1. Furthermore, the FDA requirements specifically mandated  
4 evaluation through 10 years, but the core post-approval study report schedule  
5 illustrates that reporting was only done for 6 years. *See Exhibit C*, pg. 2. The lack of a  
6 sufficient statistical sample, due to the low follow-up rate, as well as the inconsistent  
7 data and the failure to conduct the full study hampered Mentor's ability to alter the  
8 labeling and defeated the purpose of the study in assessing the 10 year long-term  
9 clinical performance of the product.

10 84. The reported findings of this study lack statistical reliability, and did so in  
11 the sub-groups (cohorts): primary augmentation, revision augmentation, primary  
12 construction, and revision reconstruction.

13 85. In the primary augmentation cohort, Mentor only reported the  
14 reasons for reoperation in 36% of the sample. Mentor failed to disclose to the FDA  
15 the reasons why only about one-third of the sample were included in this aspect of the  
16 study.

17 86. In the revision augmentation cohort, reoperation rate was 43%. Mentor  
18 reported the most common reason for reoperation, which was capsular contraction, at  
19 30.4%. Mentor failed to disclose other reasons why women in this category needed  
20 reoperation.

21 87. In the primary construction cohort, Mentor reported reoperation rates at  
22 49%. Mentor reported that of that group, 16.6 % needed reoperation because of  
23 asymmetry, 14% for capsular contraction, 12.7% for rupture, and 10.8% for breast  
24 mass. Fully 47% of women in this category needed reoperation for which Mentor  
25 failed to document or explain the reasons.

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<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm337827.htm>, last checked April 25, 2017.

1           88. In the revision reconstruction cohort, reoperation was performed on 50.7%  
2 of the women surveyed. The most frequently reported reasons were capsular  
3 contraction and breast mass totaling 36.2% of reoperations, leaving the remainder of  
4 reasons for reoperation unreported. Other reported reasons, including connective  
5 tissue and neurologic disorders and gel bleed were downplayed even though they  
6 were significant given the small sample studied.

7                   **2) Large Post-Approval Study**

8           89. The FDA's approval also required Mentor to conduct a 10-year large post  
9 approval study, consistent with a protocol submitted to the FDA by Mentor on  
10 September 26, 2006. *See Exhibit D*, Large Cohort Study.

11           90. That protocol required patient enrollment within 90 days of issuance of the  
12 PMA. The Large Post-Approval Study was to be a separate study from the Core Study  
13 and was to include 41,911 Mentor silicone gel patients and 1,017 saline-filled breast  
14 implant patients as the control group. The purpose of this study was to address  
15 specific issues for which the Core Study was not designed to fully answer,  
16 including a real-world assessment long-term local complications, such as connective  
17 tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological  
18 signs and symptoms; offspring, reproductive, and lactation issues; cancer rates,  
19 suicide, mammography issues, rupture results, and MRI compliance. The data was to  
20 be collected through annual patient questionnaires, either completed via the  
21 internet, mail, or telephone. The study also required physician evaluations at years 1,  
22 4-6, 9 and 10 to collect data on complications. Mentor was required to update their  
23 patient and physician labeling to reflect the 5 and 10-year study findings, as well as at  
24 any other time if necessary to report significantly new information from the study.

25           91. At the outset, the actual number of MemoryGel enrolled participants was  
26 approximately 41,452, almost 500 patients fewer than the PMA requirements. Mentor  
27 initiated patient enrollment in February 2007 and closed enrollment in July 2009, with  
28 a total of 41,975 silicone gel filled breast implant participants, however Mentor's data

1 included only 41,419 patients who met the original enrollment criteria because over  
2 500 were under the age of 22. *See Exhibit J.* The FDA asked Mentor provide data and  
3 analyses on these younger women in future analyses.

4 92. Enrollment by indication was 26,173 primary augmentation participants,  
5 8,382 revision-augmentation participants, 5,023 primary reconstruction participants,  
6 1,761 revision-reconstruction participants, and 113 participants did not provide  
7 important information. By year 7, the overall follow-up rate was 20.1%  
8 (approximately 8,331 participants out of 41,452), leaving 79.9% of the desired  
9 statistics unavailable for evaluation.

10 93. This was a study of significant importance required by the FDA for  
11 post market approval. The study was designed to address a critical spectrum of  
12 health issues for women with breast implants. Mentor did not comply with the  
13 required data collection. With nearly an 80% dropout rate, the study failed to  
14 collect data to demonstrate that use of the Mentor silicone gel implants was safe.  
15 The inadequate results are even more disconcerting because the data collection  
16 was designed to examine reasons for reoperation-previously unevaluated-  
17 including MRI results, and rheumatologic or neurological symptoms. The lack of  
18 participation and reliable results from this study show that Mentor has failed to  
19 comply with FDA requirements. Mentor did not follow through with data  
20 collection. The Year 1 follow-up rate of surgeon visit for MemoryGel  
21 participants was 22.8%, leaving nearly 80% unaccounted for; the Year 1, 2, and  
22 3 follow-up rates of MemoryGel patient questionnaires were 21.4%, 24.3%, and  
23 23.0%, respectively, leaving nearly 80% unaccounted for. These follow-up rates  
24 were too low for Mentor to provide meaningful safety information. At Year 7,  
25 the overall follow-up rate was 20.1%, leaving 79.9% of participants unaccounted  
26 for and did not have follow-ups for data collection. No follow-up rates were  
27 provided for the 10-year data collection.

### 3) Device Failure Study

94. In order to ascertain the reasons for and frequency of device failure, the FDA specifically required that "Mentor must continue preclinical studies to characterize the long-term modes and causes of failure of explanted retrieved devices for the 10-year duration of the large postapproval study." *See Exhibit E*, Device Failure Study. This study was to address the following specific issues: "(1) further evaluation of iatrogenic failures to address issues raised by the April 2005 Panel, (2) the characterization of when surgical instrument damage occurs, (3) further evaluation and characterization of failures due to localized shell stress, and (4) any correlation between surgical factors (e.g., incision size) and device rupture." Mentor was also required to update their patient and physician labeling to reflect any relevant findings from this study.

95. The study design involved two components: 1) the collection of implant/surgery information and clinical data at the time of explantation, and 2) visual inspection and physical testing of the explanted devices. No study population was stated, and there was no patient follow-up.

96. As of August 31, 2009, 97 core gel devices had been explanted and returned for evaluation. *See Exhibit E*. However, the post-approval Device Failure study goes on to state that for MemoryGel post-approval devices, a total of 1,545 implants (1,379 smooth and 166 textured) were retrieved *worldwide*, and not just within the United States, from November 17, 2006 through August 31, 2009. Of the 1,545 retrieved devices, 664 were from the United States and 881, or 57%, were outside the United States. *Only 62 retrieved devices, or 4%, were associated with the PAS (post-approval study) patients*, and 1,483 devices, or 95%, were associated with non-PAS patients or international patients. *See Exhibit E*, pg. 1.

97. Mentor's Device Failure post-approval study failed to contain an adequate sample size to provide meaningful data.

1           98. Mentor's Device Failure post-approval study report of summary findings  
2 to the FDA did not list results of the data findings (no clinical data and no visual  
3 inspection data), did not list safety findings, did not list any recommendations or  
4 summary of safety and data or follow-up on the data, and did not list any changes to  
5 labeling, all in violation of this condition established in the approval of Mentor's  
6 PMA.

7           99. Overall, Mentor blatantly failed to meet the FDA's requirements. Mentor  
8 merely filed a report with minimal information just to show that they were following  
9 reporting protocol.

#### 10                   4) **Focus Group Study**

11           100. This condition required Mentor to complete a focus group study of  
12 the augmentation and reconstruction patient groups. *See Exhibit F*, Focus Group  
13 Study. An independent group was to obtain responses from patients on the adequacy  
14 of the format and content of the approved labeling. Upon completion of the focus  
15 group study, Mentor was to provide a report of the findings and a revised patient and  
16 physician labeling based on those findings.

17           101. Mentor used only 35 women to evaluate how patients understood the  
18 safety and labeling brochures. The study used two methods of data collection-  
19 discussion groups and self-administered surveys. Endpoints included participants'  
20 reactions to the layout and format of the brochures, content order, illustrations, and  
21 tables. Data was to be collected on their comprehension and perceived relevance of  
22 the content. Some respondents concluded that the true purpose of the brochure was to  
23 protect Mentor, rather than inform patients about the risks of breast implant surgery.  
24 Respondents reported that the information on the labeling did not help them  
25 understand the risks and complications associated with breast implants. They also  
26 reported that most of the information did not help them weigh the relative importance  
27 of risks and complications associated with breast implants. Respondents also felt the  
28 brochure fell short of providing information on the benefits of breast implants and did

1 not acknowledge the deeply personal benefits of body image and self-esteem,  
2 especially for women who lose their breast to cancer.

3 102. The recommendations for labeling changes included adding information  
4 clearly describing differences between restoration, replacement, reconstruction, and  
5 revision early in the main body of the brochure; adding information on potential  
6 complications based on the likelihood of occurrence; providing more information  
7 about benefits; and providing more qualitative information to help women make  
8 more informed decisions.

9 103. Despite the long list of recommendations for labeling changes, no further  
10 tests were done. Moreover, the small number of women studied and the blatant  
11 disregard for the recommendations for labeling exemplifies that the PMA  
12 requirements were not met by Mentor.

### 13 5) **Informed Decision Study**

14 104. The Informed Decision Study required Mentor to distribute their approved  
15 patient labeling to all physicians intending to use the silicone gel products. *See*  
16 *Exhibit G*, Informed Decision Study. It was designed as a random survey of 50  
17 physicians on an annual basis to determine the success of the informed decision  
18 process provided to women who seek breast implant surgery. Both the physician and  
19 the patient were intended to sign designated sections in order to best assure that the  
20 patient had obtained the labeling in sufficient time prior to surgery to read it and  
21 understand the risks and other information associated with the Mentor device.

22 105. Mentor was to conduct the survey randomly, selecting 50 physicians on an  
23 annual basis, collect the results and provide a summary of the findings to the FDA  
24 under the condition the FDA was to evaluate the findings and advise Mentor if and  
25 when the annual survey was no longer necessary. In addition, Mentor was to provide  
26 training on this process as part of their physician training program.

27 106. The study protocol parameters indicated there were no follow-up visits in  
28 the study.



1 107. The summary of findings filed by mentor did not list the sample size of  
 2 patients enrolled. It only provided insight for one year (2011) and reported that 54  
 3 surveys were returned by 50 physicians and did not list what went into the survey or  
 4 which points were assessed. Mentor provided minimal information on the outcome.

#### 5 6) **Mentor Adjunct Study**

6 108. The final condition imposed by the FDA required Mentor to continue the  
 7 adjunct study. *See Exhibit H*, Adjunct Study. This study was originally designed  
 8 to serve a public health need for reconstruction and revision patients, but because  
 9 that need was no longer an issue (because of the PMA), Mentor was required to: (1)  
 10 cease new patient enrollment into the study, and (2) continue to follow-up on all  
 11 currently-enrolled Mentor Adjunct Study patients through 5 years. The data from the  
 12 follow-up study was to be reported as part of the annual reports required by the PMA.

13 109. The Adjunct Study was designed to follow-up with patients post-  
 14 operatively at years 1, 3, and 5 to assess satisfaction and occurrence of local  
 15 complications. The study was to gather data regarding short-term and local (tissue)  
 16 implant complications. Clinical endpoints for years 1, 3, and 5 follow-ups included  
 17 infection, seromas, ruptures, and capsular contracture; for years 3 and 5 follow-ups  
 18 were rheumatological/immunologic symptoms.

19 110. While a large number of patients were enrolled in the Adjunct Study,  
 20 designed to address the public health needs of reconstruction and revision patients  
 21 before device approval and to gather safety data regarding short-term post-implant  
 22 complications, the overall patient follow-up rates at Year 1 was 44%, Year 3 was  
 23 24.7%, and Year 5 was 13.8%, meaning that at Year 5, 86.2% of the patients were not  
 24 included in the follow-up data. Mentor reported to the FDA that "poor patient  
 25 compliance significantly limited interpretation of the available safety results."

#### 26 **E. Defendant Mentor Violated the Conditions of the Product's PMA**

27 111. Mentor's duty to the scientific community and women who have  
 28 undergone augmentation for any reason - at the insistence of the FDA - was to design

1 an effective study. It was Mentor's obligation to design and execute a study where  
2 women were able to access internet forms that are easily understood and provide a  
3 working forum to report their experience with implants. Mentor intentionally and  
4 systematically failed to make this happen which is a violation of the FDA's conditions  
5 for approval. *See Exhibit B.* Data collection was sparse and potential serious side  
6 effects and harmful complications were downplayed and under-reported due to  
7 inadequate sample size and low follow-up rates.

8 112. All six of these studies were supposed to support long-term safety. The  
9 poor follow-up rates and inadequate data confirm Mentor's intentional and systematic  
10 failure to follow FDA requirements for post-approval studies.

11 113. For instance, halfway through the ten-year prospective post-marketing  
12 studies mandated by the FDA, well over 50% of the 80,000 women in the study  
13 groups were dropped or otherwise eliminated from the studies. Of the patients who  
14 were accounted for, significant numbers reported systemic ailments which can only  
15 be attributed to gel bleed introducing known toxins including silicone, heavy metals  
16 and chemicals into their bodies. Mentor was aware, or should have been aware that  
17 the gel contained chemicals and metals toxic to the human body but failed to  
18 adequately report that to the FDA and warn their patients of their dangerous  
19 consequences.

20 114. Upon information and belief, a Mentor chemist of 15 years reported to the  
21 FDA that the implants are more likely to break than the company reported. It has also  
22 been reported that the silicone is more likely to leak, even when the implants are  
23 intact, and that platinum used in the implants is more dangerous than reported. Mentor  
24 knew of these risks associated with implants, but covered them up by terminating  
25 studies, sponsoring only self-serving research they could control, and by  
26 misrepresenting the risks to the users, physicians, and regulatory agencies.

**F. Defendants' Actions Violated Federal and State Regulations Governing the Device and also Violated California State Law**

115. Defendants have a duty under California law to exercise reasonable care in warning Plaintiffs and/or Plaintiffs' physicians about the dangers of products that were known or knowable to Defendants at the time of distribution. Defendants here failed to do so.

116. Defendants also have a duty under California law to law to exercise reasonable care in the manufacture, development, design, marketing, labeling, distributing, and sale of the product. Defendants here failed to do so.

117. Defendants also had the obligations and the ability under federal regulations to maintain labeling that provides adequate warnings about risks and instructions for use; to ensure that the product was manufactured utilizing Good Manufacturing Practices; to conduct prompt, accurate and thorough post-market surveillance; to take action to ensure that the device can be used safely in accordance with the instructions; to maintain quality controls to adequately address, investigate, and assess the product's performance post-market; and to ensure that any labeling, warranties, or representations Defendants made were not false or misleading in any respect. Defendants conduct here failed to meet these federal obligations and also violated California law.

118. Mentor, as the device manufacturer, failed to comply with the post-market conditions imposed on it by the FDA to continue to monitor the use of its product to determine the safety and effectiveness, and to report any findings of adverse health consequences that may be attributable to the product to the FDA.

119. Mentor failed to report adverse events from the six new or ongoing studies commissioned as part of the product's PMA approval, which would have led to adverse event reports revealing the product's contribution to serious injury. This demonstrates a continued violation of the requirements issued by the FDA.

120. Defendants' conduct violated the conditions of the MemoryGel Silicone Breast Implant's PMA and federal regulations and requirements governing the post-

1 marketing conduct, including, but not limited to, 21 CFR §§ 820.90 et seq.; 21 CFR  
 2 §§ 814 et seq; 21 CFR §§ 820.198 et seq.; §§ 820. 100 et seq.; 21 CFR §§ 820.20 et  
 3 seq.; 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.184 et seq.; and 21 CFR §§ 820.30.  
 4 Defendants' conduct separately violated their duties under California law.

5 121. Defendants conduct violated these FDA regulations and also separately  
 6 violated its duties under California state law, thereby jeopardizing the health of  
 7 patients, including Plaintiff.

8 122. Defendants failed to timely submit post-approval studies. Defendant's  
 9 actions violated the conditions of the PMA, and federal regulations and requirements  
 10 governing the post-marketing conduct of Defendants, including, but not limited to, 21  
 11 CFR §§ 814.80 et seq. Defendants' actions also separately violated duties under  
 12 California law governing their post-market conduct.

13 123. The FDA also requires that upon purchase of a company holding a PMA,  
 14 the PMA sponsor "must submit a PMA amendment to notify the FDA of the new  
 15 owner... The... supplement should include: the effective date of the ownership  
 16 transfer; a statement of the new owner's commitment to comply with all the  
 17 conditions of approval applicable to the PMA; and either a statement that the new  
 18 owner has a complete copy of the PMA including all amendment, supplements, and  
 19 reports or a request for a copy from the FDA files."

20 124. Upon information and belief, no PMA supplement notifying the FDA of  
 21 Mentor's acquisition was submitted. These actions violated the conditions of the  
 22 PMA and federal regulations and requirements governing the post-marketing conduct  
 23 of Mentor, including, but not limited to, 21 CFR §§ 814.39 et seq. Defendants'  
 24 actions also separately violated duties under California law governing their post-  
 25 market conduct.

26 125. As presented above, Defendants failed to comply with several of the  
 27 aforementioned conditions of the PMA and federal regulations, thereby invalidating  
 28 the PMA.

1           126. To protect the Mentor MemoryGel Silicone Breast Implant brand,  
2 Defendants made a conscious and intentional decision to hide their knowledge of  
3 serious safety risks from the FDA and public.

4           127. The FDA's Office of Regulatory Affairs ("ORA") is the lead office for all  
5 field activities, including inspections and enforcement. During an inspection, if ORA  
6 investigators observe conditions they deem to be objectionable, these observations are  
7 required to be listed on an FDA Form 483 when they indicate that an FDA-regulated  
8 product may be in violation of FDA requirements.

9           128. FDA Form 483s typically are discussed with a company's management  
10 team at the conclusion of the inspection. The Form 483 is not an all-inclusive list of  
11 every possible deviation from law and regulation. There may be other objectionable  
12 conditions that exist that are not cited on the FDA Form 483. Companies must take  
13 corrective action to address the cited objectionable conditions and any related, non-  
14 cited objectionable conditions that exist.

15           129. In or around May 1, 2000 to May 10, 2000, the FDA conducted an  
16 inspection of Defendant Mentor's facility, noting conditions that it found  
17 objectionable and/or constituted violations of the FDCA and related Acts and  
18 Regulations. The Form 483 Report was issued May 10, 2000, addressed to the  
19 President of Mentor for the Manufacturing Operations Division, and noted that  
20 Mentor did not have approved software and system requirements.

21           130. In or around April 16, 2001 to April 23, 2001, the FDA conducted an  
22 inspection of Defendant Mentor's facility, noting conditions that it found  
23 objectionable and/or constituted violations of the FDCA and related Acts and  
24 Regulations. The Form 483 Report was issued April 23, 2001, addressed to Ramon  
25 Ricart, Vice President of Quality and Regulatory Assurance, and noted use of  
26 nonconforming products.

27           131. In or around February 4, 2002 to February 15, 2002, the FDA conducted  
28 an inspection of Defendant Mentor's facility, noting conditions that it found



1 objectionable and/or constituted violations of the FDCA and related Acts and  
 2 Regulations. The Form 483 Report was issued February 15, 2002, addressed to  
 3 Ramon Ricart, Vice President of Quality and Regulatory Assurance.

4 132. In or around April 16, 2003 to April 22, 2003, the FDA conducted an  
 5 inspection of Defendant Mentor's facility, noting conditions that it found  
 6 objectionable and/or constituted violations of the FDCA and related Acts and  
 7 Regulations. The Form 483 Report was issued April 22, 2003, addressed to Al  
 8 Saalabi, Vice President of Regulatory and Quality Assurance.

9 133. In or around April 13, 2004 to April 30, 2004, the FDA conducted an  
 10 inspection of Defendant Mentor's facility, noting conditions that it found  
 11 objectionable and/or constituted violations of the FDCA and related Acts and  
 12 Regulations. The Form 483 Report was issued April 30, 2004, addressed to Clarke L.  
 13 Scherff, Vice President of Regulatory Compliance, citing that:

- 14 a. Documents did not include data or statistical rationale to support their  
 15 sampling plans used to test saline and gel-filled mammary prosthetic  
 16 finished devices manufactured at Mentor.

17

18 **OBSERVATION 2**

19 Risk analysis is incomplete.

20 For example:

21 A. Silicone Gel-Filled Mammary Prosthesis Failure Modes and Effect Analysis (FMEA) included  
 22 with the Quality Risk Management Report for Gel-Filled Mammary Prostheses, Document No.  
 HS350.040129.04 (Revision 0, Date 02/10/04), does not include or consider as part of the risk  
 analysis the manufacturing process as the failure cause for the failure mode "won't sterilize".  
 The Quality Risk Management Report indicates the risk analysis (FMEA) will include potential  
 hazards associated with the design, construction, manufacture, use and misuse, packaging,  
 sterilization, and labeling of the product.

23 B. Silicone Gel-Filled Mammary Prosthesis Failure Modes and Effect Analysis (FMEA) included  
 24 with the Quality Risk Management Report for Gel-Filled Mammary Prostheses, Document No.  
 HS350.040129.04, does not include or consider, as part of the risk analysis, the effects of the  
 manufacturing process on the failure cause "absence of material" for the failure mode "fails to  
 contain gel". The risk analysis only considers the design aspects for the failure cause "absence of  
 material". The Quality Risk Management Report indicates the risk analysis (FMEA) will include  
 potential hazards associated with the design, construction, manufacture, use and misuse.

25

26 **SEE REVERSE** *3/19/04* *MRD* *PLS* **DATE ISSUED** 04/30/2004  
**OF THIS PAGE**

27 FORM FDA 483 (07-00) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** PAGE 2 OF 4 PAGES

28

1 b. Mentor did not initiate or conduct corrective action to reassess the results  
2 and adjust the values of the product bioburden samples taken between  
3 11/23/98 to 2/26/02.

4 c. Mentor did not adhere to their Environmental Monitoring Program  
5 procedure.

6 134. The FDA Establishment Inspection Report for the 13-day, April 13, 2004  
7 to April 30, 2004 inspection was issued to Mr. Clarke L. Scherff, Mentor's Vice  
8 President of Regulatory Compliance, and stated the following, but not limited to:

9 a. The inspection of the Class III medical device manufacturer was initiated  
10 by the Pre-Approval Coordinator, for PMA No. P030053.

11 b. The purpose of the premarket inspection was to assure compliance with  
12 the device current good manufacturing practices (cGMPs), placing  
13 emphasis on validation of all significant manufacturing processes  
14 conducted on the gel-filled mammary implants.

15 c. In the FDA Form 483 that was issued, four observations were cited for  
16 deficiencies in the sampling methods followed for finished device testing,  
17 risk analysis content, investigation of non-conformances, and  
18 environmental monitoring control procedures. At the conclusion of the  
19 inspection on 4/30/0-4, the Form 483 was issued to Mr. Clare L. Scherff  
20 and discussed with the management representatives of the Mentor  
21 Corporation.

22 d. Mentor's responsible individuals included:

23 i. Clark Scherff, VP Regulatory Compliance

24 ii. Al Saalabi, VP Quality and Regulatory Assurance

25 iii. Andrew G. Tymkiw, VP Manufacturing & General Manager Texas  
26 Operations

27 iv. Donald Cox, Director Quality and Regulatory Assurance

28 v. Udo Graf, Director of Research & Development

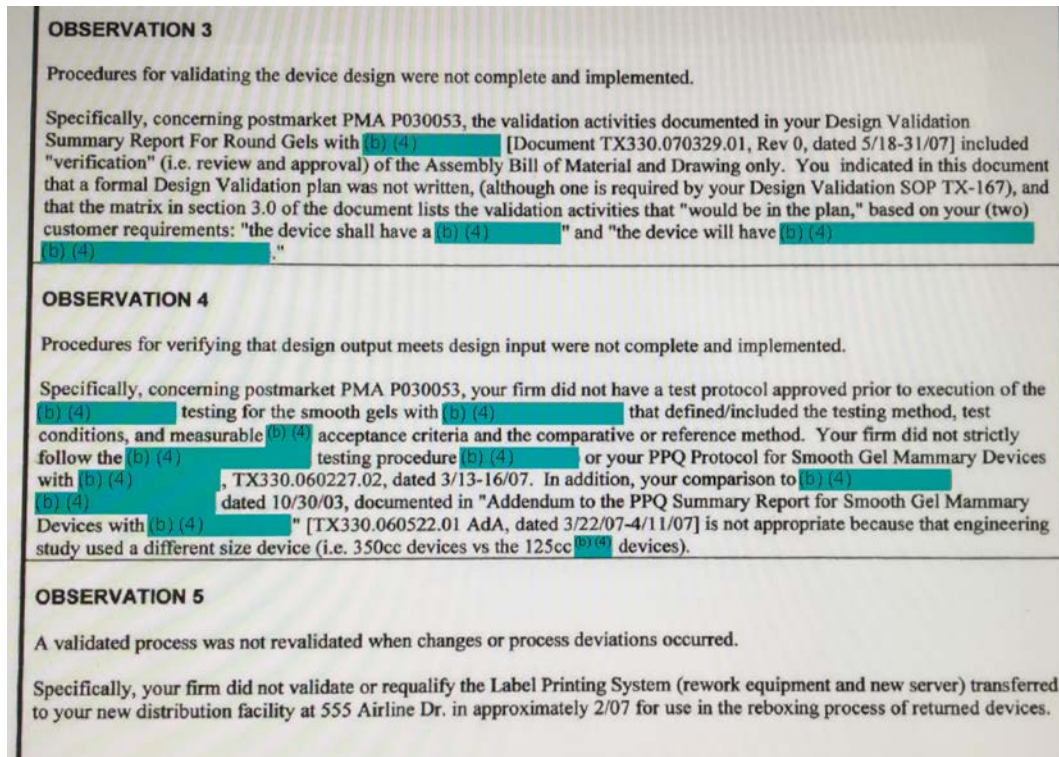


vi. Michael Megura, Director Manufacturing Engineering

e. The data provided to justify the performance of finished device testing on a Skip Lot Sampling Plan for gel-filled products is incomplete and lacks a statistical or technical rationale.

135. In or around November 7, 2007 to December 7, 2007, the FDA conducted an inspection of Defendant Mentor's facility, noting conditions that it found objectionable and/or constituted violations of the FDCA and related Acts and Regulations. The Form 483 Report was issued December 7, 2007, addressed to Steven L. Jackson, Director of Regulatory Compliance and Quality Assurance. This Form 483 noted the following violations:

<b>OBSERVATION 1</b>	
Process validation activities and results have not been fully documented.	
Specifically,	
a) Concerning pre-approval PMA (b) (4), your firm did not document the rationale why the PQ and PPQ were not required for the validation of the (b) (4) Mixer/gel mixing process for the (b) (4) implants (and per your SOP TX 111). Your qualification of the gel filling process (b) (4) Mixer (IQ/OQ protocol dated 12/13/06, report dated 9/12-17/07), did not meet the acceptance criteria: "the acceptable value for the elastomer process challenge testing is (b) (4);" however, you documented that the elastomer (b) (4) results were conforming and that the (b) (4) Mixer is capable and fully qualified to produce any future elastomer.	
b) Your Change Order #13914 [initiated 7/23/07, approved 9/17/07, and effective 10/2/07] for a Process Change, describing Change No. 2 as: "Release the new (b) (4) drawing for filling Soft Solid" and Change No. 3 as "Release the drawing for the (b) (4) elastomer filler," did not document a proper justification of the change or if process validation is required, or reference the validation/qualification assessment, for change description No. 2 and No. 3. Additionally, the Process and Product Validation section 6.9 of the last update of your design and development plan for the (b) (4) implants [approved 6/25/07] stated: "An assessment qualification is being written for the gel-filling process. Gel filling process will not be validated as appropriate rationale exists for a similar process." Your firm did not have the qualification assessment of the gel filling process documented or completed at the time of this FDA inspection.	
<b>OBSERVATION 2</b>	
Procedures were not completed for the documentation and validation or verification of design changes before their implementation.	
Specifically, concerning pre-approval PMA (b) (4) your Change Order #13918 [initiated 8/9/07 and implemented 9/19/07] for a design change describing Change no. 1 as "Adding the extra-small, extra-large, new medium and large (b) (4) (b) (4) mandrels to the DRWG103009," did not document the justification for not running additional (fill weight/volume)	
<b>SEE REVERSE OF THIS PAGE</b>	DATE ISSUED 12/07/2007
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136. Defendants' actions violated duties under federal law, federal regulations, and California law.

### **G. Defendants Intentionally and Knowingly Failed to Warn Patients and Physicians**

137. Arsenic, antimony, barium, cobalt, mercury, nickel, copper, zinc, chromium, titanium, vanadium, selenium, tin, and molybdenum are chemical constituents of Mentor's silicone-gel implants and/or are present in the implants as a relic of the manufacturing process. Absent silicone gel bleed beyond that which Mentor disclosed to the FDA, heavy metals at the levels present in a patient's body, including Plaintiff, would not be found.

138. Mentor's Product Insert Data Sheet regarding the implants state that "[s]mall quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse ("bleed") through an intact implant shell.....Mentor performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact

1 MemoryGel Breast Implants into the body....Over 99% of the LMW silicones and  
 2 platinum stayed in the implant. The overall body of available evidence supports that  
 3 the extremely low level of gel bleed is of no clinical consequence." *See Exhibit I*,  
 4 Product Insert Data Sheet, pg. 19.

5 139. The nature and extent of Plaintiff's injuries evidence a significant gel  
 6 bleed, as opposed a bleed of "small quantities" of gel, or "extremely low level of gel  
 7 bleed."

8 140. Mentor failed to warn consumers, healthcare providers, and the FDA that a  
 9 significant gel bleed was a potential risk of a properly manufactured MemoryGel  
 10 Silicone Gel Breast Implant.

11 141. The risk of a significant gel bleed was not disclosed or discussed in what  
 12 Mentor calls its "Directions for Use" or in its consumer labeling, despite the  
 13 availability of substantial evidence that such was a significant potential risk of use,  
 14 even in a properly manufactured product, was present.

15 142. Gel-filled implants, including MemoryGel, enable gel bleed even through  
 16 an intact shell which results in microdispersion. Implant ruptures cause  
 17 macrodispersions, which can make the patient, including Plaintiff, gravely ill.

18 143. In a June 2011 FDA report on breast implants entitled "FDA Update on  
 19 the Safety of Silicone Gel-Filled Breast Implants," (*See Exhibit J*, FDA Update), the  
 20 FDA pointed out, among other things, that:

- 21 a. Patient follow-up rates were lower than anticipated, which limited the  
 22 ability to draw definitive conclusions and to detect complications.
- 23 b. The primary goals of the FDA's post-market medical device surveillance  
 24 are to identify previously unrecognized adverse events and to help detect  
 25 patterns of actual or potential adverse events.
- 26 c. Mentor must submit adverse event reports on silicone gel-filled breast  
 27 implants received after November 2006 through one of two reporting  
 28 methods:
  - i. Medical Device Reports (MDR)- manufacturers must report all  
 deaths and unusual, unique, or uncommon adverse events to the

FDA as individual reports on the FDA Form 3500A within 30 days of becoming aware of the event, or

- ii. Postmarket Spreadsheet Reports (PSR)- manufacturers must report serious injuries and malfunctions that are well-known or expected to occur based on data from the premarket clinical trials in PSR reports. PSR reports are submitted quarterly, as authorized under 21 CFR Part 803.19(c), as an alternative to the requirement for submitting individual MDR reports on FDA Form 3500A.

1. The FDA designed the PSR program specifically to monitor the postmarket performance of approved silicone gel-filled breast implants. The PSR program, an alternative to the requirement for submitting individual MDR reports, requires manufacturers to submit quarterly reports for serious injuries and malfunctions that are well-known or expected to occur based on data from the premarket clinical trials (e.g., rupture, capsular contracture).

- d. Because the number of patient and device problems reported to the FDA is subject to underreporting, MAUDE and PSR data are not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices.

144. The FDA advised that, since Mentor began post-approval studies in 2007, Mentor found 43.5% of implants retrieved from patients participating in the large post-approval study had ruptures, and 25% of 97 implants that were explanted and returned to Mentor for evaluation from August 2000 to August 2009 in the Core Study had ruptured.

145. Based upon Mentor's reports, the FDA separately stated that "The most common cause of rupture reported in the device retrieval studies is damage to the implant during the implantation surgery. However, only a small proportion of breast implants are returned to the manufacturers for evaluation. This limits the ability to identify trends in failure modes." It is unclear what "damage to the implant during surgery" means, whether due to the foreseeable handling of the devices, weakness in the shell due to manufacturing defects, or other foreseeable factors.



1 146. Mentor knew of multiple risks associated with implants, and  
 2 responded by terminating post-market studies, failing to conduct required follow-up,  
 3 sponsoring only self-serving research they could control, and by misrepresenting the  
 4 risks to the users, physicians, and regulatory agencies. Mentor's duty to the scientific  
 5 community and women who have undergone augmentation for any reason-at the  
 6 insistence of the FDA-was to design an effective study.

7 147. Mentor intentionally and systematically failed to make this happen which  
 8 is a violation of the FDA's directives for compliance with the conditions of approval  
 9 of the PMA.

#### 10 **V. PLAINTIFF REXINA MIZE'S INJURIES**

11 148. Plaintiff Rexina Mize underwent a bilateral breast augmentation procedure  
 12 on September 27, 2000, wherein Mentor MemoryGel® Silicone breast implants (the  
 13 "product") were implanted by Defendant Neal Handel M.D. in Los Angeles,  
 14 California. *See Exhibit K*, Product Identification Labels.

15 149. Upon information and belief, and as informed by Defendant Mentor on  
 16 June 30, 2017, Plaintiff was allegedly a participant in Mentor's Adjunct Study, which  
 17 was unknown to her because Defendant Dr. Handel did not inform her of this material  
 18 information at the time of her implant surgery.

19 150. Upon information and belief, Ms. Mize was not contacted for follow-up  
 20 information as a participant in Defendant Mentor's Adjunct study. According to  
 21 Mentor's study design, "The Adjunct study is a 5-year study, in which patients will be  
 22 followed at 1, 3, and 5 years postoperatively to assess satisfaction and occurrence of  
 23 local complications." *See Exhibit H*.

24 151. In fact, the "Interim Safety Information" states that "a total of 136,609  
 25 patients implanted with MemoryGel breast implants for reconstruction and revision-  
 26 reconstruction were enrolled in the Adjunct study. The overall patient follow-up rates  
 27 at 1, 3 and 5 years were 35.7%, 24.0% and 16.0% respectively." *See Exhibit H*.

28 152. Upon information and belief, Defendant Mentor did not conduct follow-up

1 with Ms. Mize. Furthermore, Defendant Dr. Handel did not inform Ms. Mize that she  
2 was a participant in this study.

3 153. Ms. Mize sought breast implants for primary augmentation purposes, not  
4 for “reconstruction and revision-reconstruction” as the Adjunct study was designed  
5 for. Therefore, her inclusion in Mentor’s Adjunct study was improper.

6 154. Prior to her breast augmentation, Plaintiff enjoyed an active, full life, and  
7 did not experience any of the symptoms she would soon experience after her  
8 implants. Plaintiff was a musician and a singer in a band, and performed often.

9 155. When Ms. Mize presented to Dr. Handel for a breast augmentation, she  
10 was not told she would be part of a clinical study. Had Dr. Handel told Ms. Mize of  
11 this material information, and that the breast implants were not yet FDA-approved  
12 devices, Ms. Mize would not have undergone the implant procedure.

13 156. Dr. Handel intentionally concealed material information from Ms. Mize,  
14 including but not limited to, that she would be part of Mentor’s clinical study and that  
15 the breast implants she received were not yet FDA-approved. Thus, Ms. Mize did not  
16 give her informed consent to undergo such a procedure.

17 157. Subsequently after her implant surgery with the product, she began  
18 experiencing extreme and chronic fatigue, muscle pain, muscle weakness, muscle  
19 cramps, bone pain, swelling in her joints, pain in her joints, stiffness in her joints,  
20 severe memory loss, mental confusion, irritability, shortness of breath, severe  
21 migraines, itching, nausea, dizziness, numbness in her extremities, vision dysfunction,  
22 skin rashes, signs of silicone toxicity, autoimmune issues, weight gain, hormonal  
23 problems, heart palpitations, and extreme sensitivity to coldness. Plaintiff’s vision  
24 was so compromised that she had to get glasses in order to see. Plaintiff’s chronic  
25 fatigue was so pervasive and continuous that there were many days she could not  
26 even get out of bed in the morning. Plaintiff had to give up her music and singing in  
27 the band as a result of the chronic fatigue and other symptoms which prevented her  
28 from performing. Plaintiff also missed several business opportunities due to the

1 presence of her chronic symptoms. Plaintiff maintains a health and nutritious diet at  
 2 all times relevant. Plaintiff reported these symptoms to her physician throughout the  
 3 years since her implant surgery. Her physicians did not connect it to her Mentor  
 4 MemoryGel® silicone breast implants.

5 158. In or around the latter part of 2016, Plaintiff reported to her physician that  
 6 her left implant was causing her severe pain. Her physician ordered an MRI. On or  
 7 about December 6, 2016, Plaintiff had an MRI to assess her bilateral breast implants,  
 8 which revealed bilateral subpectoral silicone implants demonstrating rupture of the  
 9 right implant.

10 159. On or about a blood test from December 29, 2016, Plaintiff's sed rate was  
 11 elevated above the normal reference range.

12 160. On or about January 3, 2017, Plaintiff underwent explant surgery to  
 13 remove the bilateral silicone breast implants. The procedure entailed a bilateral total  
 14 capsulectomy and implant removal. Her postoperative diagnosis revealed there was a  
 15 right extracapsular and left intracapsular rupture of the silicone breast implants. As  
 16 noted in the operative report, "both implant capsular complexes were examined.  
 17 There was obvious silicone present on the outer capsule of the right side. Both  
 18 capsules were incised. There was obvious free silicone gel on the right side and  
 19 surprisingly some stranding of the silicone gel on the left side as well. Closer  
 20 examination of the left implant showed smooth, round, 400 cc of silicone implant  
 21 with a small hole. The right side showed smooth, round, 400 cc silicone gel implant  
 22 with large tear."

23 161. On or about January 5, 2017, the surgical pathology report from the  
 24 bilateral implant removal surgery performed on January 3, 2017 reported the  
 25 following diagnosis:

- 26 a. Left breast, capsulectomy – hyalinized fibrous tissue with calcifications,
- 27 foamy macrophages, and focal chronic inflammation.
- 28 b. Right breast, capsulectomy – hyalinized fibrous tissue with histiocytic



1 reaction to foreign material, calcifications, and focal chronic inflammation.

2 162. After her surgery, the majority of Plaintiff's symptoms and injuries caused  
3 by the Mentor silicone implants have improved, but Plaintiff is still working to get her  
4 health back. Plaintiff no longer requires glasses in order to see, and her chronic  
5 fatigue has been decreased, even during the healing process after the explant surgery.  
6 Plaintiff's mental clarity has improved.

## 7 **VI. CAUSES OF ACTION**

### 8 **FIRST CAUSE OF ACTION**

#### 9 **NEGLIGENCE & NEGLIGENCE PER SE**

10 **(Plaintiff Rexina Mize As Against Defendant MENTOR WORLDWIDE LLC)**

11 163. Plaintiffs incorporate by reference all previous and subsequent paragraphs  
12 of this Complaint as if fully set forth here and further alleges as follows:  
13

14 164. At all relevant times, Defendants had a duty to Plaintiff to use reasonable  
15 care in formulating, making, creating, labeling, packaging, testing, constructing,  
16 assembling, advertising, manufacturing, selling, distributing, marketing, and  
17 promoting Mentor MemoryGel Silicone Gel Breast Implants.

18 165. Defendants formulated, made, created, labeled, packaged, tested,  
19 constructed, assembled, advertised, manufactured, sold, distributed, marketed, and  
20 promoted Mentor MemoryGel Silicone Gel Breast Implants, including the product that  
21 was implanted into Plaintiff Rexina Mize.

22 166. Defendants had a duty under parallel state law, including California law, to  
23 exercise reasonable care to provide adequate warning about the risks and dangers of  
24 Mentor MemoryGel Silicone Gel Breast Implants that were known or knowable to  
25 Defendants at the time of distribution.

26 167. Defendants breached their duty in that they failed to warn Plaintiffs and  
27 their physicians by not reporting the risk of serious defects and life-altering  
28 complications described herein that Defendants knew or should have known were

1 associated with Mentor MemoryGel Silicone Gel Breast Implants prior to the time of  
 2 Plaintiff's implantation, including the actual level of risk and failure to communicate  
 3 adverse events similar to the injuries suffered by Plaintiff.

4 168. Specifically, upon information and belief, Defendants breached these  
 5 duties and violated federal and state law by, inter alia: receiving and failing to warn of  
 6 or report adverse events to the FDA or the public; failing to warn of or report Mentor  
 7 MemoryGel Silicone Gel Breast Implants failure to meet its performance  
 8 specifications or perform as intended under the PMA and FDA requirements; and  
 9 receiving and failing to warn or report to the FDA and the medical community their  
 10 knowledge and information regarding complaints about Mentor MemoryGel Silicone  
 11 Gel Breast Implants, including but not limited to:

- 12 a. instances of ruptured;
- 13 b. instances of silicone toxicity;
- 14 c. instances of adverse events;
- 15 d. instances of adverse events requiring removal;
- 16 e. instances of constellations of adverse symptoms;
- 17 f. instances of chronic/persistent autoimmune-like complaints and  
 18 inflammatory issues;

19 169. Despite the fact that evidence existed that Mentor MemoryGel Silicone  
 20 Gel Breast Implants were dangerous and likely to place users at serious risk to their  
 21 health, Defendants failed to disclose and warn of the health hazards and risks  
 22 associated with Mentor MemoryGel Silicone Gel Breast Implants. Instead,  
 23 Defendants manufactured, marketed, sold, advertised, and promoted Mentor  
 24 MemoryGel Silicone Gel Breast Implants while failing to warn or otherwise ensure  
 25 the safety of its users in violation of state law, including California law, the Mentor  
 26 MemoryGel Silicone Gel Breast Implants PMA, and FDA regulations.

27 170. In addition, the Mentor MemoryGel Silicone Gel Breast Implant's PMA  
 28 set forth six specific studies and reporting requirements - as described above - that

1 obligated Defendants to report their results.

2 171. Defendants negligently failed to comply with the above requirements and  
3 failed to take necessary actions - such as filing PMA Supplements, unilaterally  
4 updating its labeling through the CBE Process, or timely submitting MDRs - to advise  
5 users of Mentor MemoryGel Silicone Gel Breast Implants of the defects and risks  
6 described above.

7 172. Defendants had the ability and the duty under state law to disclose its  
8 knowledge of adverse events to healthcare providers and the public to ensure its  
9 labeling and product were not misbranded. Health & Saf. Code, §§ 111440 (“it is  
10 unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug  
11 or device that is misbranded”), 111445 (“it is unlawful for any person to misbrand any  
12 drug or device.”).

13 173. Under parallel federal law, Defendants had the ability to disclose its  
14 knowledge of adverse events to healthcare providers and the public to ensure its  
15 labeling and product were not misbranded. 21 U.S.C. § 331 (“the following acts and  
16 the causing thereof are prohibited: (a) the introduction...of any device that is  
17 ...misbranded, (b) the ...misbranding of any ...device...).

18 174. Had Defendants timely and adequately reported the adverse events to the  
19 FDA, it would have effectively warned physicians of those adverse events both  
20 directly and through discussion of those events that would have followed in the  
21 literature and at meetings. Thus, additional information would have been available to  
22 the public, including Plaintiff’s physician, regarding the dangers of Mentor  
23 MemoryGel Silicone Gel Breast Implants that were known or knowable to  
24 Defendants at the time of distribution.

25 175. If Plaintiff had been adequately warned of the serious risks and adverse  
26 events by Defendant Mentor, she would not have agreed to implantation of Mentor  
27 MemoryGel Silicone Gel Breast Implants. As a proximate and legal result of  
28 Defendants’ failure to comply with its PMA and FDA post-marketing regulations,

1 Defendants breached their duty of care to Plaintiff under parallel state law and caused  
2 Plaintiff past and future suffering, including severe physical injuries, severe emotional  
3 distress, mental anguish, economic loss, and other injuries for which she is entitled to  
4 compensatory and other damages in an amount to be proven at trial.

5 176. Defendants owed a duty in all of their several undertakings, including the  
6 communication of information concerning Mentor MemoryGel Silicone Gel Breast  
7 Implants, and to exercise reasonable care to ensure that they did not, in those  
8 undertakings, create unreasonable risks of personal injury to others.

9 177. Defendants, in the course of their business and profession, knowingly and  
10 negligently disseminated inaccurate and misleading information to physicians  
11 concerning the properties and effects of Mentor MemoryGel Silicone Gel Breast  
12 Implants, with the intent and expectation that physicians would rely on that  
13 information in their decisions in recommending and surgically implanting Mentor  
14 MemoryGel Silicone Gel Breast Implants in their patients.

15 178. When Defendants disseminated information to physicians and/or patients  
16 concerning the properties and effects of Mentor MemoryGel Silicone Gel Breast  
17 Implants, they knew or should have known that physicians and/or patients would  
18 reasonably rely on that information in their decisions concerning the use of Mentor  
19 MemoryGel Silicone Gel Breast Implants.

20 179. Defendants disseminated false information, in that they engaged in false  
21 and misleading sales and marketing tactics, touting the aesthetic beauty of breast  
22 augmentation and minimizing the risks, which reached physicians, the medical  
23 community, and the public with knowledge that the information was, in fact, false and  
24 misleading.

25 180. Defendants produced false and misleading sales and marketing tactics and  
26 concealed adverse information at a time when Defendants knew, or should have  
27 known, that Mentor MemoryGel Silicone Gel Breast Implants had defects, dangers,  
28 and characteristics that were other than what Defendants had represented to

1 consumers and the healthcare industry generally.

2 181. Defendants had no reasonable grounds for believing these representations  
3 were true when they were made; in fact, Defendants knew the representations to be  
4 false.

5 182. Defendants' breach of their duties under state law parallel to their  
6 violations of federal law; the Mentor MemoryGel Silicone Gel Breast Implants PMA  
7 specifically mandates, and state law independently requires, that any representations  
8 regarding the device must be truthful, accurate, and not misleading, and must be  
9 consistent with applicable federal and state laws.

10 183. Defendants disseminated the false information, as referenced above, to  
11 physicians, the medical community, and the public with the intention to deceive  
12 physicians and their patients and to induce physicians to surgically implant Mentor  
13 MemoryGel Silicone Gel Breast Implants.

14 184. In willfully supplying the false and misleading information, Defendants  
15 negligently failed to exercise reasonable care to ensure that the information  
16 disseminated to physicians and patients concerning the properties and effects of  
17 Mentor MemoryGel Silicone Gel Breast Implants was accurate and not misleading.

18 185. By failing to ensure representations regarding Mentor MemoryGel  
19 Silicone Gel Breast Implants were truthful, accurate, and not misleading, Defendants  
20 have violated the Mentor MemoryGel Silicone Gel Breast Implants PMA, FDA  
21 regulations, and parallel state law.

22 186. Defendants expected or should have expected that patients, in reliance on  
23 false information, who were implanted with Mentor MemoryGel Silicone Gel Breast  
24 Implants would be placed in unnecessary, avoidable, and unreasonable danger due to  
25 unwarranted exposure to Mentor MemoryGel Silicone Gel Breast Implants, causing  
26 them to undergo future removal surgeries.

27 187. Plaintiff and/or Plaintiff's physicians did in fact reasonably rely on  
28 Defendants' negligent misrepresentations, as Defendants intended.

1 188. As a proximate and foreseeable result of the foregoing misrepresentations  
 2 by Defendants, Plaintiff has suffered and will continue to suffer severe physical  
 3 injuries, severe emotional distress, mental anguish, economic loss, and other injuries  
 4 for which she is entitled to compensatory and other damages in an amount to be  
 5 proven at trial.

6 189. Under federal law and regulations, Defendants were under a continuing  
 7 duty to comply with the requirements listed in their PMA and with the FDCA in the  
 8 manufacture, development, promotion, marketing, labeling, distribution, testing, and  
 9 sale of Mentor MemoryGel Silicone Gel Breast Implants. 21 U.S.C. §§ 301, et seq; 21  
 10 U.S.C. § 360l (postmarket surveillance).

11 190. Violations of the following federal regulations also constitute violations of  
 12 Defendants' parallel state law duties and give rise to negligence per se: 21 C.F.R. §  
 13 803.10; 21 C.F.R. § 803.50; 21 C.F.R. § 803.52; 21 C.F.R. §803.53; 21 C.F.R. §  
 14 803.56; 21, C.F.R. § 806; 21 C.F.R. § 814.1; 21 C.F.R. § 814.3; 21 C.F.R. § 814.9; 21  
 15 C.F.R. § 814.20; 21 C.F.R. § 814.37; 21 C.F.R. § 814.39; 21 C.F.R. § 814.80; 21  
 16 C.F.R. § 814.82; 21 C.F.R. § 814.84; 21 C.F.R. § 820.1; 21 C.F.R. § 820.5; 21 C.F.R.  
 17 § 820.20; 21 C.F.R. § 820.22; 21 C.F.R. § 820.25; 21 C.F.R. § 820.30; 21 § C.F.R.  
 18 820.70; 21 § 820.90; and 21 C.F.R. § 820.160.

19 191. Defendants' conduct also violates their duties under the Sherman Food,  
 20 Drug, and Cosmetic laws and gives rise to negligence per se. West's Ann. Cal. Health  
 21 & Safety Code §§ 109875, et. seq.; 111260; 111295; 111300; 111305; 111440;  
 22 111445; and 111450.

23 192. Plaintiff is within the class of persons the statutes and regulations protect,  
 24 and Plaintiff's injuries are of the type of harm these statutes and regulations are  
 25 designed to prevent.

26 193. Defendants' violations of these statutes and regulations proximately  
 27 caused Plaintiff's injuries alleged herein.

28 194. The conditions of the Mentor MemoryGel Silicone Gel Breast Implants

1 PMA incorporate these statutes and regulations. Failure to comply with the  
2 conditions of approval invalidates the PMA. See 21 C.F.R. § 814.82(c).

3 195. Defendants had a parallel duty under state law, including California law, to  
4 exercise reasonable care in testing and inspecting their product, in monitoring  
5 conformity with the design of Mentor MemoryGel Silicone Gel Breast Implants  
6 placed into Plaintiff, in performing continuing risk-analysis and risk assessments of  
7 Mentor MemoryGel Silicone Gel Breast Implants, in manufacturing Mentor  
8 MemoryGel Silicone Gel Breast Implants, and in marketing Mentor MemoryGel  
9 Silicone Gel Breast Implants to the public.

10 196. Defendants were negligent under state law, including California law, in  
11 their development, promotion, marketing, manufacture, distribution, and/or sale of  
12 Mentor MemoryGel Silicone Gel Breast Implants in one or more of the following  
13 particulars:

- 14 a. manufacturing actual Mentor MemoryGel Silicone Gel Breast Implants  
15 that differ from the specifications set forth in the PMA, its Supplements,  
16 the Conditions of Approval, and/or other federal regulations;
- 17 b. manufacturing actual Mentor MemoryGel Silicone Gel Breast Implants  
18 with nonconforming materials and uncertified components, inconsistent  
19 with the specifications set forth in the PMA, its Supplements, the  
20 Conditions of Approval and/or other federal regulations;
- 21 c. failing to conduct regular risk analysis of Mentor MemoryGel Silicone Gel  
22 Breast Implant;
- 23 d. failing to properly meet the applicable standard of care by not complying  
24 with applicable federal regulations;
- 25 e. carelessly and negligently selling and distributing Mentor MemoryGel  
26 Silicone Gel Breast Implants in violation of the PMA and federal law;
- 27 f. negligently incorporating components into Mentor MemoryGel Silicone  
28 Gel Breast Implants that could not stand up to normal usage;



1 g. failing to exercise reasonable care in its inspecting and testing of the  
2 product; and

3 h. failing to exercise reasonable care in its manufacturing and quality control  
4 processes.

5 197. Despite the fact that Defendants knew or should have known that Mentor  
6 MemoryGel Silicone Gel Breast Implants caused unreasonable, dangerous side effects,  
7 Defendants continued to promote and market Mentor MemoryGel Silicone Gel Breast  
8 Implants to consumers, including Plaintiff, and their healthcare providers.

9 198. Defendants also had a duty under state law, including California law, to  
10 exercise ordinary care in the manufacture of Mentor MemoryGel Silicone Gel Breast  
11 Implants consistent with FDA specifications, the Mentor MemoryGel Silicone Gel  
12 Breast Implants PMA, and/or conditions of approval.

13 199. At all relevant times, Defendants were required to comply with the FDA's  
14 Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. §  
15 820.1, et seq., which, among other things, require that each manufacturer put  
16 procedures in place to test products for compliance with product specifications,  
17 document and check compliance with product specifications before products are  
18 accepted for sale and use, and identify and control all products that fail to conform with  
19 product specifications.

20 200. The Mentor MemoryGel Silicone Gel Breast Implants contained a  
21 manufacturing defect when it left Defendants' possession, in that Defendants'  
22 manufacturing process did not conform to the FDA's current good manufacturing  
23 practices ("cGMP") design controls enumerated in 21 C.F.R. § 820.30.

24 201. Upon information and belief, Defendant Mentor has received several Form  
25 483 violations and establishment inspection reports ("EIR") which exemplified its  
26 failing to comply with statutes and regulations.

27 202. Defendants failed to exercise ordinary care in the manufacture, sale, testing,  
28 quality assurance, quality control, and/or distribution of Mentor MemoryGel Silicone

1 Gel Breast Implants. For instance, on August 3, 2016, a Class 2 recall was issued for  
2 the Mentor MemoryGel Breast Implants, recall number Z-2326-2016. *See Exhibit L*,  
3 Recall Notice. This recall was based on labeling mix-ups, including that the box of  
4 300cc MemoryGel Breast Implants were labeled with null manufacturing and  
5 expiration dates. Products subject to this recall were distributed in New York,  
6 Wisconsin, California, Texas, Colorado, North Carolina, New Jersey, Ohio, Tennessee,  
7 Rhode Island, and Illinois.

8 203. Defendants failed to adequately inspect, test, and validate the materials and  
9 components used in the manufacture and assembly of Mentor MemoryGel Silicone Gel  
10 Breast Implants.

11 204. Defendants failed to adequately inspect, test, and validate Mentor  
12 MemoryGel Silicone Gel Breast Implants after completion of assembly and  
13 immediately before delivery for implantation into Plaintiff.

14 205. Defendants failed to comply with the regulations and testing requirements  
15 imposed by the granting of the PMA by the FDA for the Mentor MemoryGel Silicone  
16 Gel Breast Implants, including the requirement that follow-through studies be  
17 conducted. Upon information and belief, Plaintiff may have been a participant in the  
18 Core Study, and was not contacted for follow-up.

19 206. Because Defendants failed to follow specifications, regulations, and  
20 required Good Manufacturing Practices, Plaintiff's Mentor MemoryGel Silicone Gel  
21 Breast Implants were vulnerable to degradation, deterioration, ruptures, and leakage.

22 207. Upon information and belief, when Mentor MemoryGel Silicone Gel Breast  
23 Implants was manufactured, Defendants had the technological capability to  
24 manufacture Mentor MemoryGel Silicone Gel Breast Implants in a reasonably safe  
25 manner and is held to the level of knowledge of an expert in the field. Defendant Mentor  
26 touts itself as a global leader in aesthetic medicine. For over 20 years, more than 5  
27 million women have used Mentor breast implants, making Mentor one of the global  
28 leaders in breast aesthetics.

208. Upon information and belief, Plaintiff was implanted with Mentor MemoryGel Silicone Gel Breast Implants with manufacturing defects, manufactured with nonconforming materials and uncertified components, in violation of the PMA specifications and regulatory requirements, resulting in product failure and serious injury to Plaintiff. The injuries Plaintiff suffered are expected to result from the manufacturing defects identified therein. Plaintiff and her physician were unaware that the device was defective at the time of implant and for years thereafter.

209. As a proximate and legal result of Defendants' failure to exercise reasonable care and the resulting defective condition of Mentor MemoryGel Silicone Gel Breast Implants implanted into Plaintiff caused Plaintiff's injuries described infra, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future follow-up medical care, medical treatment, and procedures, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

210. WHEREFORE, Plaintiff prays for judgment against Defendants as hereinafter set forth.

## **SECOND CAUSE OF ACTION**

### **STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

#### **(Plaintiff Rexina Mize As Against Defendant MENTOR WORLDWIDE LLC)**

211. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

212. At all times relevant herein, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Mentor MemoryGel Silicone Gel Breast Implants.

213. At all times relevant herein, Defendants intended for the MemoryGel Silicone Gel Breast Implants to be surgically implanted into the bodies of members of

1 the general public, including Plaintiff, and knew or should have known that the  
2 product would be surgically implanted into members of the general public, including  
3 Plaintiff.

4 214. Defendants failed to warn Plaintiff and her physicians of the risk of serious  
5 defects and life altering complications described herein rendering the device defective  
6 and unreasonably dangerous.

7 215. Defendants also failed to revise their labeling to warn of the accurate rate  
8 of occurrence of adverse events based upon the post-market adverse event  
9 information available to them.

10 216. Plaintiff's Mentor MemoryGel Silicone Gel Breast Implants was defective  
11 at the time of sale and distribution and at the time they left the possession of  
12 Defendants in that Defendants failed to adequately warn of the risks that the product  
13 was vulnerable to degradation, deterioration, ruptures, and leakage, and other injuries  
14 associated with Mentor MemoryGel Silicone Gel Breast Implants. The MemoryGel  
15 Silicone Gel Breast Implants were defective and unreasonably dangerous when they  
16 left the possession of Defendants in that they contained warnings insufficient to alert  
17 consumers, including Plaintiff, of the dangerous risks and complications associated  
18 with the MemoryGel Silicone Gel Breast Implants, including but not limited to, their  
19 propensity to cause injury, through leakage of the silicone gel into the tissues of the  
20 user's body, thereby introducing toxic metals and chemicals into those tissues,  
21 resulting in serious, dangerous and harmful side effects and complications all to the  
22 detriment of the health and well-being of the users of their product, including  
23 Plaintiff.

24 217. Defendants knew or should have known the gel contained in the  
25 implants contained metals and toxic chemicals in such quantities that would be  
26 extremely harmful to users of their product if the gel were allowed to escape its shell  
27 and "bleed" into the user's body. Defendants also knew or should have known that  
28 there was a significant risk of rupture or seepage of the gel through the shell and into

1 the tissues of the user's body. Defendants failed to adequately warn users, including  
2 Plaintiff, of Defendants' products and of these potential serious and harmful risks.

3 218. Defendants failed to provide follow-through post-approval studies required  
4 by the FDA's granting of the PMA necessary in order to market and sell their product,  
5 and thus failed to report to, and warn, the FDA of the risks described above.

6 219. The accurate rate of occurrence for these and other injuries associated with  
7 Mentor MemoryGel Silicone Gel Breast Implants were not readily recognizable to the  
8 ordinary consumer, including Plaintiff and/or Plaintiff's physician, as a result of  
9 Defendants' conduct.

10 220. Mentor MemoryGel Silicone Gel Breast Implants were defective and  
11 unreasonably dangerous due to inadequate warnings and/or instruction because  
12 Defendants knew or should have known that the products created a serious risk of  
13 degradation, deterioration, ruptures, and leakage, and other injuries that could, and  
14 did, harm consumers, including Plaintiff, and Defendants failed to adequately warn  
15 consumers of said risks - including Plaintiff and/or her physician- in accordance with  
16 state law, including California law.

17 221. Mentor MemoryGel Silicone Gel Breast Implants manufactured and sold  
18 by Defendants were defective and unreasonably dangerous due to inadequate  
19 warnings and instructions because Defendants knew or should have known that  
20 Mentor MemoryGel Silicone Gel Breast Implants created, among other things, a  
21 higher than expected risk for adverse events, and Defendants failed to adequately  
22 warn of those risks, to monitor those risks, report them, test for them, and update its  
23 labeling regarding such risks when the information became available.

24 222. At all relevant times, Plaintiff's Mentor MemoryGel Silicone Gel Breast  
25 Implants were used and implanted into Plaintiff as intended by Defendants and in a  
26 manner reasonably foreseeable to Defendants.

27 223. Mentor MemoryGel Silicone Gel Breast Implants manufactured, marketed,  
28 promoted, distributed, and sold by Defendants were expected to, and did, reach

1 Plaintiff and/or Plaintiff's physician without substantial change in the condition in  
2 which they were sold.

3 224. Despite the fact that Defendants knew or should have known that the use  
4 of Mentor MemoryGel Silicone Gel Breast Implants were unreasonably dangerous  
5 and likely to place users at serious risks to their health, Defendants failed to monitor  
6 and warn of the defects, health hazards, and risks associated with Mentor MemoryGel  
7 Silicone Gel Breast Implants.

8 225. Plaintiff's Mentor MemoryGel Silicone Gel Breast Implants were also  
9 defective at the time of sale and distribution, and at the time the devices left the  
10 possession of Defendants, in that the devices differed from Defendants' intended  
11 result and design specifications.

12 226. Upon information and belief, Plaintiff was implanted with Mentor  
13 MemoryGel Silicone Gel Breast Implants with manufacturing defects, manufactured  
14 with nonconforming materials and uncertified components, in violation of the PMA  
15 specifications and regulatory requirements, resulting in product failure and serious  
16 injury to Plaintiff, requiring surgery. The injuries Plaintiff suffered are expected to  
17 result from the manufacturing defects identified therein and by the FDA. Plaintiff and  
18 her physician were unaware that the device was defective at the time of implant and  
19 for years thereafter.

20 227. Defendants violated state law, including California law, by placing the  
21 Mentor MemoryGel Silicone Gel Breast Implants into the stream of commerce in a  
22 defective and unreasonably dangerous condition.

23 228. Mentor MemoryGel Silicone Gel Breast Implants had a manufacturing  
24 defect when they left Defendants' possession in that Defendants' manufacturing  
25 process did not conform to the cGMP design controls enumerated in 21 C.F.R. §  
26 820.30.

27 229. The defects inherent in Mentor MemoryGel Silicone Gel Breast Implants  
28 were not readily recognizable to the ordinary consumer, including Plaintiff and/or

1 Plaintiff's physician.

2 230. Plaintiff could not, in the exercise of reasonable care, have discovered the  
3 defects herein mentioned and perceived their true danger.

4 231. Plaintiff and/or Plaintiff's physician reasonably relied upon the skill,  
5 superior knowledge, and judgment of Defendants, including Defendant Mentor, when  
6 she consented to the implantation procedure using Mentor MemoryGel Silicone Gel  
7 Breast Implants.

8 232. At all relevant times, Plaintiff's Mentor MemoryGel Silicone Gel Breast  
9 Implants were used and implanted as intended by Defendants and in a manner  
10 reasonably foreseeable to Defendants.

11 233. Had Plaintiff and/or Plaintiff's physician received adequate warnings  
12 regarding the risks the risks of Mentor MemoryGel Silicone Gel Breast Implants, she  
13 would not have used them.

14 234. Mentor MemoryGel Silicone Gel Breast Implants manufactured, designed,  
15 promoted, marketed, distributed, and sold by Defendants were expected to, and did,  
16 reach Plaintiff and/or Plaintiff's physician without substantial change in the condition  
17 in which they were sold.

18 235. Defendants knew that Mentor MemoryGel Silicone Gel Breast Implants  
19 would be used by the ordinary purchaser or user without inspection for defects and  
20 without knowledge of the hazards involved in such use.

21 236. At all times relevant to this action, the dangerous propensities of Mentor  
22 MemoryGel Silicone Gel Breast Implants were known to Defendants or were  
23 reasonably and scientifically knowable to them, through appropriate research and  
24 testing by known methods, at the time they distributed, supplied, or sold the device,  
25 and not known to ordinary physicians who would be expected to implant Mentor  
26 MemoryGel Silicone Gel Breast Implants for their patients.

27 237. Defendants were required to provide adequate warnings to consumers and  
28 the medical community under federal and state law, including California law, but



1 failed to do so in a timely and responsible manner.

2 238. Had Defendants timely and adequately reported adverse events to the  
3 FDA, there would have been effective warnings to physicians, including Plaintiff's  
4 physician, of those adverse events both directly and through discussion of those  
5 events that would have followed in the literature and at meetings. Thus, additional  
6 information would have been available to the public, including Plaintiff and/or  
7 Plaintiff's physician, regarding the dangers of Mentor MemoryGel Silicone Gel  
8 Breast Implants that were known or knowable to Defendants at the time of  
9 distribution.

10 239. Because Defendants failed to follow specifications, regulations, and  
11 required Good Manufacturing Practices, Plaintiff's Mentor MemoryGel Silicone Gel  
12 Breast Implants were vulnerable to degradation, deterioration, ruptures, and leakage.

13 240. Mentor MemoryGel Silicone Gel Breast Implants, which was  
14 manufactured, distributed, tested, sold, marketed, promoted, advertised, and  
15 represented defectively by Defendants, was a substantial contributing factor in  
16 bringing about Plaintiff's injuries, which would not have occurred but for the use of  
17 Mentor MemoryGel Silicone Gel Breast Implants.

18 241. The defective warnings were a substantial contributing factor in bringing  
19 about the injuries to Plaintiff that would not have occurred but for the use of Mentor  
20 MemoryGel Silicone Gel Breast Implants.

21 242. The defective manufacturing was a substantial contributing factor in  
22 bringing about the injuries to Plaintiff that would not have occurred but for the use of  
23 Mentor MemoryGel Silicone Gel Breast Implants.

24 243. As a proximate result and/or substantial factor of Mentor MemoryGel  
25 Silicone Gel Breast Implants defective condition at the time they were sold, Plaintiff  
26 suffered and will continue to suffer severe physical injuries, severe emotional distress,  
27 mental anguish, economic loss, future medical care and treatment, and other injuries  
28 for which she is entitled to compensatory and other damages in an amount to be

1 proven at trial.

2 244. By reason of the foregoing, Plaintiff has been damaged by Defendants'  
3 wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the  
4 very least arose to the level of gross negligence so as to indicate a disregard of the  
5 rights and safety of others, justifying an award of punitive damages.

6 245. The wrongful acts, representations and/or omissions of Defendants,  
7 hereinabove set forth, were made, adopted, approved, authorized, endorsed and/or  
8 ratified by Defendants' officers, directors, or managing agents, and were done  
9 maliciously, oppressively, fraudulently and/or with a willful and knowing disregard  
10 of the probably dangerous consequences for the health and safety of its products  
11 users, including Plaintiff. In making, adopting, approving, authorizing, endorsing  
12 and/or ratifying such conduct hereinabove set forth, the officers, directors and/or  
13 managing agents of Defendants acted with a willful and/or knowing disregard of  
14 the probably dangerous consequences, and/or acted with an awareness of the  
15 probably dangerous consequences of their conduct and deliberately dialed to avoid  
16 those consequences, thereby creating a substantial risk of injury to Plaintiff and other  
17 users of their products. Plaintiffs are entitled to punitive and exemplary damages in an  
18 amount to be ascertained, which is appropriate to punish to set an example of  
19 Defendants and deter such behavior by them in the future.

20 246. WHEREFORE, Plaintiffs prays for judgment against Defendants as set  
21 forth.

### 22 **THIRD CAUSE OF ACTION**

#### 23 **STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

#### 24 **(Plaintiff Rexina Mize As Against Defendant MENTOR WORLDWIDE LLC)**

25 247. Plaintiff incorporates by reference all previous and subsequent paragraphs  
26 of this Complaint as if fully set forth here and further alleges as follows:

27 248. At all times relevant herein, Defendants were engaged in the  
28 business of designing, developing, manufacturing, testing, packaging, promoting,

1 marketing, distributing, labeling, and/or selling Mentor MemoryGel Silicone Gel  
2 Breast Implants.

3 249. At all times relevant herein, Defendants intended for the MemoryGel  
4 Silicone Gel Breast Implants to be surgically implanted into the bodies of members of  
5 the general public, including Plaintiff, and knew or should have known that the  
6 product would be surgically implanted into members of the general public, including  
7 Plaintiff.

8 250. Defendants manufactured, tested, marketed, promoted, advertised,  
9 distributed, and sold the Mentor MemoryGel Silicone Gel Breast Implants that were  
10 implanted into Plaintiff.

11 251. At all times relevant, Defendant placed Mentor MemoryGel Silicone Gel  
12 Breast Implants into the stream of commerce, and did so in a manner in which the  
13 Mentor MemoryGel Silicone Gel Breast Implants were defective in their  
14 manufacturing due to not meeting the current good manufacturing practices required  
15 by the FDA under the terms and conditions of the PMA.

16 252. Defendants violated state law, including California law, by placing the  
17 Mentor MemoryGel Silicone Gel Breast Implants into the stream of commerce in a  
18 defective and unreasonably dangerous condition.

19 253. Defendants' Mentor MemoryGel Silicone Gel Breast Implants implanted  
20 during Plaintiff's surgery contained a manufacturing defect. The rupture, leakage, and  
21 bleeding of silicone of the Mentor MemoryGel Silicone Gel Breast Implants  
22 implanted into Plaintiff, due to porous or weak containment in the Implant shell, is  
23 inconsistent with specifications and conditions of the product submitted in the PMA  
24 to the FDA for approval, and therefore constitutes a manufacturing defect.

25 254. Defendants' actions, hereinafter described, violate the FDA's Quality  
26 System Regulations and Current Good Manufacturing Practices, 21 C.F.R. § 820.1, et  
27 seq., which, among other things, require that each manufacturer put procedures in  
28 place to test products for compliance with product specifications, document and

1 check compliance with product specifications before products are accepted for sale  
2 and use, and identify and control all products that fail to conform with product  
3 specifications.

4 255. Defendants knew that the defect was such that it would not be discovered  
5 through reasonable inspection by the users of the product, including Plaintiff.  
6 Defendants knew that Mentor MemoryGel Silicone Gel Breast Implants would be  
7 used by the ordinary purchaser or user without inspection for defects and without  
8 knowledge of the hazards involved in such use.

9 256. Plaintiff and Plaintiff's physician, foreseeable users and ultimate  
10 consumers of the Defendants' product, were unaware of these defects when Plaintiff  
11 consented to have them implanted in her body.

12 257. As a direct and legal result of the manufacturing defects contained in their  
13 MemoryGel Silicone Gel Breast Implants, Plaintiff was injured in her health and well-  
14 being as described hereinabove when the toxins contained in the gel began to seep  
15 into the tissues of her body, causing a constellations of symptoms and injuries.

16 258. As a proximate result and/or substantial factor of Mentor MemoryGel  
17 Silicone Gel Breast Implants defective condition at the time they were sold, Plaintiff  
18 suffered and will continue to suffer severe physical injuries, severe emotional distress,  
19 mental anguish, economic loss, future medical care and treatment, and other injuries  
20 for which she is entitled to compensatory and other damages in an amount to be  
21 proven at trial.

22 259. By reason of the foregoing, Plaintiff has been damaged by Defendants'  
23 wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the  
24 very least arose to the level of gross negligence so as to indicate a disregard of the  
25 rights and safety of others, justifying an award of punitive damages.

26 260. The wrongful acts, representations and/or omissions of Defendants,  
27 hereinabove set forth, were made, adopted, approved, authorized, endorsed and/or  
28 ratified by Defendants' officers, directors, or managing agents, and were done

maliciously, oppressively, fraudulently and/or with a willful and knowing disregard of the probably dangerous consequences for the health and safety of its products users, including Plaintiff. In making, adopting, approving, authorizing, endorsing and/or ratifying such conduct hereinabove set forth, the officers, directors and/or managing agents of Defendants acted with a willful and/or knowing disregard of the probably dangerous consequences, and/or acted with an awareness of the probably dangerous consequences of their conduct and deliberately dialed to avoid those consequences, thereby creating a substantial risk of injury to Plaintiff and other users of their products. Plaintiffs are entitled to punitive and exemplary damages in an amount to be ascertained, which is appropriate to punish to set an example of Defendants and deter such behavior by them in the future.

261. WHEREFORE, Plaintiffs prays for judgment against Defendants as hereinafter set forth.

#### **FOURTH CAUSE OF ACTION**

##### **BREACH OF IMPLIED WARRANTY**

##### **(Plaintiff Rexina Mize As Against Defendant MENTOR WORLDWIDE LLC)**

262. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

263. At all relevant times, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, marketed, advertised, and sold Mentor MemoryGel Silicone Gel Breast Implants.

264. Prior to Plaintiff's implantation of Mentor MemoryGel Silicone Gel Breast Implants, Defendants impliedly warranted to Plaintiff and Plaintiff's health care providers that Mentor MemoryGel Silicone Gel Breast Implants was of merchantable quality, reasonably fit for its intended purpose, and safe for the use for which it was intended.

265. Defendants also warranted that Mentor MemoryGel Silicone Gel Breast

1     Implants was safer and more effective than other prior generations of breast implants.

2             266. At all relevant times, Plaintiff and Plaintiff's physician used and implanted  
3     Mentor MemoryGel Silicone Gel Breast Implants for the purpose and in the manner  
4     intended by Defendants.

5             267. At all relevant times, Mentor MemoryGel Silicone Gel Breast Implants  
6     was not reasonably safe for its expected purpose, nor reasonably fit for the ordinary  
7     purpose for which it was sold and/or used and it did not meet the expectations for the  
8     performance of the product when used in a customary, usual and reasonably  
9     foreseeable manner.

10            268. Plaintiff and/or her healthcare provider reasonably relied upon the skill  
11     and judgment of Defendants and upon said warranties in using Mentor MemoryGel  
12     Silicone Gel Breast Implants.

13            269. Defendants' breaches of their implied warranties under state law parallel  
14     their violations of federal law; the Mentor MemoryGel Silicone Gel Breast Implants  
15     PMA specifically mandates, and state law, including California law, independently  
16     requires, that any warranty statements must be truthful, accurate, and not misleading,  
17     and must be consistent with applicable federal and state laws.

18            270. As soon as the true nature of Mentor MemoryGel Silicone Gel Breast  
19     Implants and the fact that the warranties and representations were false was  
20     ascertained, Defendants were on notice of the breach of said warranties.

21            271. As a direct and legal result of the manufacturing defects contained in their  
22     MemoryGel Silicone Gel Breast Implants, Plaintiff was injured in her health and well-  
23     being as described hereinabove when the toxins contained in the gel began to seep  
24     into the tissues of her body, causing a constellations of symptoms and injuries.

25            272. As a proximate result and/or substantial factor of Mentor MemoryGel  
26     Silicone Gel Breast Implants defective condition at the time they were sold, Plaintiff  
27     suffered and will continue to suffer severe physical injuries, severe emotional distress,  
28     mental anguish, economic loss, future medical care and treatment, and other injuries



1 for which she is entitled to compensatory and other damages in an amount to be  
2 proven at trial.

3 273. By reason of the foregoing, Plaintiff has been damaged by Defendants'  
4 wrongful conduct. Defendants' conduct was willful, wanton, reckless, and, at the  
5 very least arose to the level of gross negligence so as to indicate a disregard of the  
6 rights and safety of others, justifying an award of punitive damages.

7 274. WHEREFORE, Plaintiffs prays for judgment against Defendants as set  
8 forth.

### 9 **FIFTH CAUSE OF ACTION**

#### 10 **LOSS OF CONSORTIUM**

#### 11 **(Spouse Plaintiff Minh Nguyen as Against All Defendants)**

12 275. Plaintiffs incorporate by reference all other paragraphs of this complaint as  
13 if fully set forth herein and further allege as follows:

14 276. At all relevant times hereto, Spouse Plaintiff MINH NGUYEN was and is  
15 the lawful spouse of Plaintiff REXINA MIZE.

16 277. As a result of the injuries and damages suffered by Plaintiff REXINA  
17 MIZE by Defendants' defective Mentor MemoryGel Silicone Gel Breast Implants,  
18 she was unable to perform any activities as a spouse in the household. Plaintiff  
19 REXINA MIZE was unable to take care of the house or provide companionship to  
20 Spouse Plaintiff MINH NGUYEN. Spouse Plaintiff MINH NGUYEN had to take  
21 full control over chores and acts around the house, including but not limited to,  
22 laundry, dishes, cooking, errands, cleaning taking Plaintiff REXINA MIZE to medical  
23 treatment, and taking care of Plaintiff REXINA MIZE's needs. Spouse Plaintiff  
24 MINH NGUYEN effectively lost the companionship and accompaniment of his wife,  
25 Plaintiff REXINA MIZE, as a result of Defendant's defective Mentor MemoryGel  
26 Silicone Gel Breast Implants.

27 278. As a direct and proximate result of the injuries sustained by Plaintiff  
28 REXINA MIZE and caused by Defendants, Spouse Plaintiff MINH NGUYEN

1 suffered, and will continue to suffer the loss of his wife's consortium, companionship,  
2 society, affection, services and support.

3 279. WHEREFORE, Plaintiffs pray for judgment against Defendants as  
4 hereinafter set forth.

5  
6  
7 **SIXTH CAUSE OF ACTION**

8 **MEDICAL BATTERY**

9 **(Plaintiff Rexina Mize As Against Defendant Dr. Handel)**

10  
11 280. Plaintiffs incorporate by reference all other paragraphs of this  
12 complaint as if fully set forth herein and further allege as follows:

13 281. Defendant Dr. Handel performed a breast augmentation procedure  
14 on Ms. Mize in Beverly Hills, California on or about September 27, 2000 using  
15 Mentor's gel-filled breast implants, Ref. No. 350-7400BC, Lot 209120. See Exhibit  
16 K.

17 282. Defendant Dr. Handel performed this procedure without Ms. Mize's  
18 consent, since the breast implants were investigational devices and Dr. Handel did not  
19 inform Ms. Mize that she would be part of Mentor's clinical study or that the breast  
20 implants were not yet FDA-approved.

21 283. In essence, Dr. Handel performed an operation on Ms. Mize which  
22 she didn't consent to. Upon information and belief, Ms. Mize gave permission to Dr.  
23 Handel to perform one type of surgery – that is, implanting approved silicone  
24 implants – but Dr. Handel performed another surgery – that is, implanting non-  
25 approved silicone implants.

26 284. Upon information and belief, Defendant Mentor alleges that Ms.  
27 Mize was a participant in its Adjunct Study. Upon information and belief, Dr. Handel  
28 concealed this information from Ms. Mize.

285. Upon further information and belief, the Adjunct study included “a total of 136,609 patients implanted with MemoryGel breast implants for reconstruction and revision-reconstruction were enrolled in the Adjunct study. The overall patient follow-up rates at 1, 3 and 5 years were 35.7%, 24.0% and 16.0% respectively.” See Exhibit H.

286. Ms. Mize sought breast implant surgery from Dr. Handel for primary augmentation purposes, not for “reconstruction and revision-reconstruction” as the Adjunct study was designed for. Therefore, her inclusion in Mentor’s Adjunct study was improper.

287. As a direct result of Defendant Dr. Handel’s conduct, Ms. Mize suffered physical injuries.

288. As a proximate result and/or substantial factor of Dr. Handel’s conduct, Plaintiff suffered and will continue to suffer severe physical injuries, severe emotional distress, mental anguish, economic loss, future medical care and treatment, and other injuries for which she is entitled to compensatory and other damages in an amount to be proven at trial.

289. By reason of the foregoing, Plaintiff has been damaged by Defendant Dr. Handel’s wrongful conduct. Defendant Dr. Handel’s conduct was willful, wanton, reckless, and, at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

290. WHEREFORE, Plaintiffs prays for judgment against Defendants as set forth.

### **SEVENTH CAUSE OF ACTION**

#### **FAILURE TO OBTAIN INFORMED CONSENT**

#### **(Plaintiff Rexina Mize As Against Defendant Dr. Handel)**

291. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein and further allege as follows:

1           292. Defendant Dr. Handel was negligent because he performed a breast  
2 implant surgery on Ms. Mize without first obtaining her informed consent.

3           293. Defendant Dr. Handel performed a breast augmentation procedure  
4 on Ms. Mize in Beverly Hills, California on or about September 27, 2000 using  
5 Mentor's gel-filled breast implants, Ref. No. 350-7400BC, Lot 209120. See Exhibit  
6 K.

7           294. Dr. Handel intentionally concealed material information from Ms.  
8 Mize, including but not limited to, that she would be part of Mentor's clinical study  
9 and that the breast implants she received were not yet FDA-approved. Thus, Ms. Mize  
10 did not give her informed consent to undergo such a procedure.

11           295. Defendant Dr. Handel failed to obtain Ms. Mize's informed consent  
12 for this surgery because he did not inform Ms. Mize that she would be included as a  
13 participant in Defendant Mentor's clinical study, and that the breast implants were not  
14 approved medical devices.

15           296. Had Dr. Handel told Ms. Mize that the breast implants she received  
16 were not FDA-approved medical devices and that she would have to be part of a  
17 clinical study, Ms. Mize would not have consent to, or undergone the surgery.

18           297. Further, Ms. Mize presented to Dr. Handel for primary  
19 augmentation purposes, not for "reconstruction and revision-reconstruction" as the  
20 Adjunct study was designed for. Therefore, Dr. Handel's implant surgery was  
21 improper.

22           298. As a direct result of Defendant Dr. Handel's conduct, Ms. Mize  
23 suffered physical injuries.

24           299. As a proximate result and/or substantial factor of Dr. Handel's  
25 conduct, Plaintiff suffered and will continue to suffer severe physical injuries, severe  
26 emotional distress, mental anguish, economic loss, future medical care and treatment,  
27 and other injuries for which she is entitled to compensatory and other damages in an  
28 amount to be proven at trial.

1           300. By reason of the foregoing, Plaintiff has been damaged by Defendant Dr.  
 2 Handel's wrongful conduct. Defendant Dr. Handel's conduct was willful, wanton,  
 3 reckless, and, at the very least arose to the level of gross negligence so as to indicate a  
 4 disregard of the rights and safety of others, justifying an award of punitive damages.

5           301. WHEREFORE, Plaintiffs prays for judgment against Defendants as set  
 6 forth.

### 7 8 **REQUEST FOR PUNITIVE DAMAGES**

9           302. Plaintiffs incorporate by reference all other paragraphs of this complaint as  
 10 if fully set forth herein and further alleges as follows:

11           303. At all times relevant herein, Defendants, and each of them:

- 12           a. failed to properly conduct post-approval studies;
- 13           b. knew or should have known that Mentor MemoryGel Silicone Gel Breast  
 14           Implants were dangerous and ineffective;
- 15           c. concealed the dangers and health risks from Plaintiff, physicians, other  
 16           medical providers, the FDA, and the public at large;
- 17           d. attempted to misrepresent and did knowingly make misrepresentations  
 18           to Plaintiff, physicians, and other medical providers, and the public in  
 19           general as to the safety and efficacy of Mentor MemoryGel Silicone Gel  
 20           Breast Implants;
- 21           e. with full knowledge of the health risks associated with Mentor  
 22           MemoryGel Silicone Gel Breast Implants and without adequate  
 23           warnings of the same, manufactured, formulated, tested, packaged,  
 24           labeled, produced, created, made, constructed, assembled, marketed,  
 25           advertised, distributed and sold Mentor MemoryGel Silicone Gel Breast  
 26           Implants for use;
- 27           f. intentionally concealed that Ms. Mize was to be included in Mentor's  
 28           clinical study; and

1 g. intentionally concealed that Ms. Mize was to receive non-approved  
2 medical implants.

3 304. Defendants, by and through its officers, directors, managing agents,  
4 authorized sales representatives, employees and/or other agents who engaged in  
5 malicious, fraudulent and oppressive conduct towards Plaintiff and the public, acted  
6 with willful, wanton, conscious, and/or reckless disregard for the safety of Plaintiff and  
7 the general public.

8 305. Defendants' misrepresentations included knowingly withholding material  
9 information from the medical community and the public, including Plaintiffs,  
10 concerning the safety of Mentor MemoryGel Silicone Gel Breast Implants.  
11 Defendants' conduct was willful, wanton, and undertaken with a disregard for  
12 Plaintiff's rights.

13 306. Defendants' intentional and/or reckless conduct deprived Plaintiff of  
14 necessary information to enable her to weigh the true risks of using Mentor  
15 MemoryGel Silicone Gel Breast Implants against its benefits.

16 307. As a direct and proximate result of one or more of these wrongful acts or  
17 omissions of Defendants, Plaintiff suffered profound injuries that required medical  
18 treatment and incurred medical and hospital expenses, for which Plaintiff have  
19 become liable.

20 **RELIEF REQUESTED**

21 WHEREFORE Plaintiffs pray for judgment against Defendants and, as  
22 appropriate to each cause of action alleged and as appropriate to the standing of  
23 Plaintiffs, as follows:

- 24
- 25 1) Economic and non-economic damages in an amount as provided by law and  
26 to be supported by evidence at trial;
  - 27 2) For compensatory damages according to proof;
  - 28 3) For an award of attorneys' fees and costs;



- 4) For prejudgment interest and the costs of suit;
- 5) Punitive or exemplary damages according to proof; and
- 6) For such other and further relief as this Court may deem just and proper.

Dated: August 17, 2017

By: /s/ Jennifer A. Lenze  
Jennifer A. Lenze  
Jaime E. Moss  
**LENZE MOSS, PLC**  
*Attorneys for Plaintiffs*

**DEMAND FOR JURY TRIAL**

Plaintiffs hereby demand individual trials by jury as to all claims so triable in this action.

Dated: August 17, 2017

By: /s/ Jennifer A. Lenze  
Jennifer A. Lenze  
Jaime E. Moss  
**LENZE MOSS, PLC**  
*Attorneys for Plaintiffs*

**CERTIFICATE OF SERVICE**

I hereby certify that, on August 17, 2017 a copy of the foregoing **SECOND AMENDED COMPLAINT FOR DAMAGES; DEMAND FOR JURY TRIAL** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

By: /s/ Jaime E. Moss  
Jaime E. Moss